

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL NO. 1456  
Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

*The City of New York v. Abbott Labs., et al.*  
(S.D.N.Y. No. 04-CV-06054)

*County of Suffolk v. Abbott Labs., et al.*  
(E.D.N.Y. No. CV-03-229)

*County of Westchester v. Abbott Labs., et al.*  
(S.D.N.Y. No. 03-CV-6178)

*County of Rockland v. Abbott Labs., et al.*  
(S.D.N.Y. No. 03-CV-7055)

*County of Dutchess v. Abbott Labs, et al.*  
(S.D.N.Y. No. 05-CV-06458)

*County of Putnam v. Abbott Labs, et al.*  
(S.D.N.Y. No. 05-CV-04740)

*County of Washington v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00408)

*County of Rensselaer v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00422)

*County of Albany v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00425)

*County of Warren v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00468)

*County of Greene v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00474)

*County of Saratoga v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00478)

*County of Columbia v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00867)

*Essex County v. Abbott Labs, et al.*  
(N.D.N.Y. No. 05-CV-00878)

**ANSWER AND AFFIRMATIVE  
DEFENSES OF DEFENDANT  
CHIRON CORPORATION TO  
PLAINTIFFS' REVISED FIRST  
AMENDED CONSOLIDATED  
COMPLAINT**

<i>County of Chenango v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00354)	)
	)
<i>County of Broome v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00456)	)
	)
<i>County of Onondaga v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00088)	)
	)
<i>County of Tompkins v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00397)	)
	)
<i>County of Cayuga v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00423)	)
	)
<i>County of Madison v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00714)	)
	)
<i>County of Cortland v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00881)	)
	)
<i>County of Herkimer v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00415)	)
	)
<i>County of Oneida v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00489)	)
	)
<i>County of Fulton v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00519)	)
	)
<i>County of St. Lawrence v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00479)	)
	)
<i>County of Jefferson v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00715)	)
	)
<i>County of Lewis v. Abbott Labs, et al.</i>	)
(N.D.N.Y. No. 05-CV-00839)	)
	)
<i>County of Chautauqua v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06204)	)
	)
<i>County of Allegany v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06231)	)
	)
<i>County of Cattaraugus v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06242)	)
	)
<i>County of Genesee v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06206)	)
	)
<i>County of Wayne v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06138)	)

<i>County of Monroe v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06148)	)
	)
<i>County of Yates v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06172)	)
	)
<i>County of Niagara v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06296)	)
	)
<i>County of Seneca v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06370)	)
	)
<i>County of Orleans v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06371)	)
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<i>County of Ontario v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06373)	)
	)
<i>County of Schuyler v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06387)	)
	)
<i>County of Steuben v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06223)	)
	)
<i>County of Chemung v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06744)	)
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Defendant Chiron Corporation (“Chiron”), by its undersigned counsel, hereby answers the City of New York and the captioned New York Counties’ (“Counties” or “Plaintiffs”) Revised First Amended Consolidated Complaint, dated October 5, 2007, on behalf of Chiron only as follows:

**PRELIMINARY STATEMENT**

The Revised First Amended Consolidated Complaint (the “Complaint”) improperly refers to Chiron, other defendants, and third parties on a collective basis, failing to plead allegations with requisite particularity against Chiron. This is insufficient to apprise Chiron (let alone each separate entity) of the allegations asserted against it. Chiron has nevertheless attempted to respond to Plaintiffs’ allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Chiron is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. Chiron states that it is answering Plaintiffs' allegations solely on behalf of itself, even when Plaintiffs' allegations refer to alleged conduct by Chiron and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Chiron's failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Chiron's reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Chiron denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically admitted herein, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Chiron specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Chiron has included in this Answer and Affirmative Defenses the captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

Furthermore, Chiron states that its answers are based upon, and necessarily limited by, information now available to Chiron as Case Management Order No. 33 had previously stayed discovery while Chiron's individual Motion to Dismiss the New York Complaint was pending

before the Court. Therefore, Chiron hereby gives notice that it reserves its right to amend this Answer should it deem doing so necessary during the discovery process.

These comments and objections are incorporated, to the extent appropriate, into each numbered and unnumbered paragraph of this Answer.

### **SPECIFIC RESPONSES**

To the extent that the unnumbered paragraph immediately following the Table of Contents (the “Complaint’s Introductory Paragraph”) makes allegations against Chiron, Chiron denies them, except admits that the City of New York and certain New York Counties (collectively, the “Counties”) have made allegations against a number of defendants, including Chiron, as set forth in the Complaint. To the extent that the Complaint’s Introductory Paragraph states legal conclusions, no response is required. To the extent the allegations of the Complaint’s Introductory Paragraph are directed at parties other than Chiron, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations.

### **ANSWER TO INTRODUCTION**

1. The Counties bring this action against the defendant manufacturers of prescription drugs to recover monetary damages, and for civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, and treble and punitive damages suffered by them and by the State and federal governments from 1992 to the present as a result of defendants’ fraudulent and misleading schemes that overcharge the New York State Medicaid Program (“Medicaid Program”) for prescription drugs bought on behalf of City and County residents who receive Medicaid benefits. The specific prescription drugs at issue are identified by their unique national drug codes or “NDCs” (hereinafter the “at issue NDCs”) and listed in Exhibits B1-B40 hereto, which are incorporated by reference in this First Amended Consolidated Complaint.

**ANSWER:** Chiron admits that the Counties seek to bring this action as alleged in paragraph 1 of the Complaint, but Chiron denies there is any basis for them to do so and denies that they are entitled to any relief. Chiron also admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiffs with

respect to any such NDCs contained in Exhibit B to the Complaint. Chiron further admits that it manufactures and sells prescription drug products, and that there is a separate NDC number for each dosage and package size of each drug sold by Chiron. Chiron specifically denies that it has been involved in “fraudulent and misleading schemes” or that the New York State Medicaid Program has been “overcharge[d]” for prescription drugs. Chiron further denies the remaining allegations in paragraph 1 as they pertain to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

2. The Counties, in their roles as Local Social Services Districts, play an integral part in the administration of the Medicaid Program in New York State, and pay approximately 25 percent of the Medicaid costs of New York residents. N.Y. Soc. Serv. L. §§ 367-a and 368-a; 42 U.S.C. § 1396d(b). The State pays another 25 percent, and the federal government pays 50 percent. Collectively, the County Medicaid Programs paid in excess of \$20 billion for the at-issue NDCs between 1992 and 2005 alone. *See* Exhibit A hereto.

**ANSWER:** To the extent the allegations of paragraph 2 of the Complaint state legal conclusions and/or arguments, no response is required. To the extent the allegations in paragraph 2 of the Complaint purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron admits that the federal government shares the cost of reimbursing for prescription drugs under New York State’s Medicaid Plan with the State of New York and participating Counties, and respectfully refers the Court to N.Y. Soc. Serv. L. §§ 367-a and 368-a, and 42 U.S.C. § 1396d(b), for a full and complete reading of their provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2 and therefore denies the same and demands strict proof thereof.

3. There are two relevant components of the price New York Medicaid pays for the prescription drugs at issue in this case. The first is the price initially paid by Medicaid to the Pharmacy Provider, defined below, for the drug. This price is determined by a formula contained in New York State law, and is based on wholesale price information provided by the manufacturers. N.Y. Soc. Serv. L. § 367-a(9). The second component is a rebate that drug manufacturers pay to the states pursuant to a federal statutory formula, 42 U.S.C. § 1396r-8 (the “Medicaid Rebate Statute”), and pursuant to statutorily mandated Medicaid rebate contracts that each manufacturer executes with the Secretary of Health and Human Services “on behalf of the States.” Model Rebate Agreement at 1.<sup>1</sup> The amount of the rebate is calculated by each manufacturer based on the manufacturer’s own price information and utilization data compiled by the State Medicaid Plans.

**ANSWER:** To the extent the allegations of paragraph 3 of the Complaint or its footnote state legal conclusions and/or arguments, no response is required. To the extent the allegations in paragraph 3 of the Complaint or its footnote purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9); 42 U.S.C. § 1396r-8; 56 FR 7049 (Feb. 21, 1991); and 60 FR 48442 (Sept. 19, 1995) for a full and complete reading of their provisions. To the extent a response is required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint or its footnote and therefore denies the same and demands strict proof thereof.

4. Defendants’ fraudulent schemes involve both components. Their manipulation of the Medicaid program through intentional fraudulent inflation of the various reported wholesale prices that form the bases for each of these two components has resulted in overcharges of many millions of dollars to the County Medicaid Programs.

**ANSWER:** To the extent the allegations in paragraph 4 are directed at Chiron, Chiron denies them. Chiron specifically denies that it was involved in “fraudulent schemes,” the

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<sup>1</sup> See 56 FR 7049 (Feb. 21, 1991) (reprinting text of the Model Rebate Agreement); 60 FR 48442 (Sept. 19, 1995) (discussing Model Rebate Agreement). A copy of the current standard Model Rebate Agreement, available at <http://www.cms.hhs.gov/medicaid/drugs/drebate.asp>, and substantially similar to that executed by each defendant named herein, is Exhibit E hereto.

“manipulation of the Medicaid program” or the “intentional fraudulent inflation” of wholesale prices, or that the Counties’ Medicaid Programs were “overcharge[d].” Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 4 of the Complaint and therefore denies the same and demands strict proof thereof.

5. Federal regulations require State Medicaid Programs to reimburse providers for Medicaid covered drugs at the “lower of the 1) estimated acquisition costs plus reasonable dispensing fees established by the [Single State Medicaid Agency] or 2) providers’ usual and customary charges to the general public.” 42 C.F.R. § 447.331.

**ANSWER:** To the extent the allegations of paragraph 5 of the Complaint state legal conclusions and/or arguments, no response is required. To the extent the allegations in paragraph 5 of the Complaint purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron respectfully refers the Court to 42 C.F.R. § 447.331 as it existed at the time Plaintiffs filed their initial Complaint in June 2005 for a full and complete reading of its provisions. To the extent a response is required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and therefore denies the same and demands strict proof thereof.

6. New York Social Service Law provides that if the drug dispensed is a multiple source prescription drug for which a federal upper limit (“FUL”) has been set by the Federal Centers for Medicare and Medicaid Services (“CMS”), reimbursement to Pharmacy Providers, defined below, generally will be at an amount equal to the FUL.<sup>2</sup> N. Y. Soc. Serv. L. § 367-a(9).

**ANSWER:** To the extent the allegations of paragraph 6 of the Complaint or its footnote state legal conclusions and/or arguments, no response is required. To the extent the

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<sup>2</sup> There is one important caveat to this. New York Social Services Law § 367-a(9)(c) requires that if the prescribing physician certifies that the Medicaid beneficiary must receive the brand version of the multi-source drug (by writing “brand necessary” and “DAW” on the prescription), then reimbursement to the Pharmacy Provider is based on AWP, not the FUL. Defendants’ own documents make clear that manufacturers of innovator multi-source drugs actively encourage physicians to write DAW in order to secure AWP-based reimbursement for pharmacies.

allegations in paragraph 6 of the Complaint or its footnote purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron respectfully refers the Court to N. Y. Soc. Serv. L. §§ 367-a(9) and 367-a(9)(c) for a full and complete reading of its provisions. Chiron specifically denies that it “actively encourage[s] physicians to write DAW in order to secure AWP-based reimbursement for pharmacies.” Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 6 of the Complaint or its footnote and therefore denies the same and demands strict proof thereof.

7. New York Social Services Law further provides that if the drug dispensed is a multiple source prescription drug or a brand-name prescription drug for which no FUL has been set by CMS, reimbursement to Pharmacy Providers will be at

the lower of the estimated acquisition cost of such drug to pharmacies, or the dispensing pharmacy’s usual and customary price charged to the general public. For sole and multiple source brand name drugs, estimated acquisition cost means the average wholesale price (“AWP”) of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the [New York State Department of Health], less [a certain percentage] thereof, and updated monthly by the department.

*Id.*

**ANSWER:** To the extent the allegations of paragraph 7 of the Complaint state legal conclusions and/or arguments, no response is required. To the extent the allegations in paragraph 7 of the Complaint purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron respectfully refers the Court to N. Y. Soc. Serv. L. § 367-a(9) for a full and complete reading of its provisions. To the extent a response is required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 and therefore denies the same and demands strict proof thereof.

8. At all times relevant hereto, First Data Bank has been the prescription drug pricing service used by New York State Medicaid.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 and therefore denies the same and demands strict proof thereof.

9. Defendant drug manufacturers control and unlawfully inflate the AWP and FULs that serve as the benchmarks for New York Medicaid reimbursements.

**ANSWER:** Chiron denies the allegations in paragraph 9 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it “control[s] and unlawfully inflates[s]” average wholesale prices (“AWPs”) or federal upper limits (“FULs”). To the extent the allegations in paragraph 9 of the Complaint are directed at parties other than Chiron, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

10. Manufacturers set AWP. They do this by (a) directly supplying AWP to publishers, (b) supplying publishers with a wholesale acquisition cost (“WAC”) or WAC equivalent such as direct price or list price to which the publisher applies a standard 1.2 or 1.25 mark up and/or (c) by supplying both AWP and WAC or WAC equivalent.

**ANSWER:** Chiron admits that it provided AWP for certain years to certain industry pricing compendia, or publishers, and that these publishers apply their own markups to the reported AWP. Further, Chiron avers that its AWP were not mathematical averages of prices paid by providers to acquire Chiron’s drugs. Chiron denies the remaining allegations in paragraph 10 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

11. Until recently it was generally accepted that a true WAC should be 20- 25% lower than AWP. This was understood to constitute the wholesaler mark up. This case is not about the 20-25% mark up between a true WAC and AWP to the extent that that range accurately reflects the true wholesaler mark up.

**ANSWER:** Chiron denies the allegations in paragraph 11 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

12. This case concerns, *inter alia*, that, (a) WAC itself is false and inflated and drug manufacturers know that by reporting a false and inflated WAC or WAC equivalent they can trigger the publication of a false and inflated AWP on which reimbursements are made and (b) in many cases the spread between the published WAC and the published AWP exceeds the 20-25% range. Exhibit F hereto provides examples of defendants' drugs for which AWP exceeds 1.2 or 1.25 WAC. Even these examples may be understated to the extent the WACs themselves were false.

**ANSWER:** Chiron denies the allegations in paragraph 12 of the Complaint as they pertain to Chiron and demands strict proof thereof, and states that Chiron is not listed in Exhibit F to the Complaint. Chiron specifically denies that it has "report[ed] a false and inflated WAC or WAC equivalent" to industry pricing compendia. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

13. Defendant drug manufacturers also control the FUL. This is because CMS establishes the FUL for multi-source drugs that have three or more manufacturers based on the lowest price reported by a manufacturer to any of the publishing compendia for a particular drug type. Specifically, CMS sets the FUL at "150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size." 42 CFR § 447.332. Importantly, the FUL is a per-unit price that applies to all NDCs for a particular multi-source drug. In other words, if a FUL is in place for a particular multi-source drug, all NDCs for that drug will be reimbursed at that FUL.

**ANSWER:** To the extent the allegations in paragraph 13 of the Complaint purport to recite and/or interpret laws or regulations, those laws or regulations speak for themselves, and any characterization thereof is denied. Chiron respectfully refers the Court to 42 CFR § 447.332 as it existed at the time Plaintiffs filed their initial Complaint in June 2005 for a full and complete reading of its provisions. Chiron denies the allegations in paragraph 13 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

14. Defendants' failure to submit accurate pricing data to the publishing compendia can cause false and inflated FULs to issue. It is clear that, in many instances, had defendants submitted accurate prices to pricing compendia, the FULs set by CMS would have been lower and New York State Medicaid Programs would have paid less.

**ANSWER:** Chiron denies the allegations in paragraph 14 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

15. Exhibit B to this complaint details the many examples where a specific defendant's failure to report an accurate price for its drug resulted in a false and inflated FUL being set. In each example of "FUL fraud" set forth in Exhibit B, the Counties allege that defendant's true price (or the "actual acquisition cost" "ACC") for the NDC at issue *was more than 50% lower* than the established FUL. Had the defendant reported its true price for that NDC, the operative FUL would have been based on that defendant's true price and would have been lower than it was. In such case, the County Medicaid Program's FUL-based reimbursement for that particular multi-source drug would have been less. Thus, the Counties allege FUL fraud for every NDC listed in Exhibit B where the defendant's AAC is more than 50% below the established FUL.

**ANSWER:** Chiron denies the allegations in paragraph 15 of the Complaint and Exhibit B attached thereto as they pertain to Chiron and demands strict proof thereof. Chiron is

without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint and Exhibit B attached thereto as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

16. Defendants submit false and inflated price information to the publishing compendia in order to “create a spread” between the AAC of a drug and the amount at which the drug is reimbursed.

**ANSWER:** Chiron denies the allegations in paragraph 16 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron specifically denies that it “submit[s] false and inflated price information to the publishing compendia.” Chiron further denies the characterization of “spread” in paragraph 16. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

17. Defendants know that by creating a spread they can incentivize pharmacists (both mail-order and traditional retail), Group Purchasing Organizations (“GPOs”), pharmacy benefit managers (“PBMs”), Hospital Out-Patient Pharmacies, Nursing Homes and various other Medicaid Pharmacy Providers who select among competing drugs and/or develop formularies to purchase or give preferential treatment to their products.

**ANSWER:** Chiron denies the allegations in paragraph 17 of the Complaint as they pertain to Chiron and demands strict proof thereof, except states that prescription drugs are dispensed only on a physician’s or other qualified medical professional’s order. Chiron further denies the characterization of “spread” in paragraph 17. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

18. Entities who can select among competing drug products or create formularies have substantial influence over which drug a patient ultimately receives. Entities who possess formulary power select the drug for their formularies based on spread and rebate. This is true whether the drug is single or multi-source. Geri-Med, for example, a GPO serving long term

care pharmacies makes clear in its marketing materials to its customers that one of the “Keys to Unlocking Profits” with respect to “Single Source Medications” is to “BUY THE PACKAGE SIZE WITH THE BEST AWP SPREAD”.

**ANSWER:** Chiron admits that the processes by which an entity, who can select among competing drugs products, decides what drug to dispense or by which a physician determines what prescription pharmaceutical to prescribe are complex. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 of the Complaint and therefore denies the same and demands strict proof thereof.

19. The pharmacist plays a role in deciding which drug a patient receives primarily by selecting among competing generic drugs. The pharmacist stocks the generic option with the largest spread. Often, PBMs operate mail order pharmacies and make similar drug selection choices. By selecting a drug with the greatest spread between actual acquisition cost and reimbursement rate, the PBM mail order pharmacy can collect both the PBM’s profit and the pharmacist’s.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Complaint and therefore denies the same and demands strict proof thereof.

20. The Wall Street Journal described one set of contracts involved in the sale of the antidepressant and antiobsessional generic drug fluoxetine, one of the drugs at issue here (reimbursed on AWP, not FUL) and manufactured by Defendants Barr, Novartis, Par and Teva. *See Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer ‘Discounts,’ Making \$170 On Just 90 Pills*, WSJ., March 31, 2003, at A1. The AWP for fluoxetine was \$2.66 per pill. The pharmacist could purchase fluoxetine for approximately 5 cents per pill. According to the Wall Street Journal, the health plan paid AWP minus 73%, or 60 cents per pill, to a PBM, ExpressScripts, which in turn contracted with dispensing pharmacists approved by it to pay them 25 cents per pill, or AWP minus 94%. The PBM’s profit was 35 cents per pill, and the pharmacist’s profit was 20 cents per pill.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 20 of the Complaint refer to a Wall Street Journal article, the article speaks for itself, and any characterizations

thereof are denied. Chiron respectfully refers the Court to *Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making \$170 On Just 90 Pills*, WSJ., March 31, 2003, at A1 for a full and complete reading of its contents.

21. In 2003 alone, the Counties spent over \$8.2 million on fluoxetine manufactured by these defendants. Exhibit B reveals fluoxetine spreads as high as 25,581%. *See, for example*, Exhibit B-6.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint and therefore denies the same and demands strict proof thereof.

22. Wholesalers likewise establish formularies and auto-substitution programs (often on behalf of retail pharmacists) and otherwise make efforts to promote particular drugs so as to maximize their profits.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint and therefore denies the same and demands strict proof thereof.

23. By secretly polluting the entire reimbursement system with false and inflated prices, defendants improperly and unlawfully have caused the Medicaid Program to subsidize these improper incentives for the purchase of defendants' products.

**ANSWER:** Chiron denies the allegations in paragraph 23 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has "secretly polluted the entire reimbursement system with false and inflated prices." Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

24. Defendants long have deliberately concealed that they create the spread in this way, and have deliberately concealed that the reason they cause false and inflated published

reimbursement prices to issue is to create spreads between actual cost and reimbursement amounts that permit defendants to influence market share. As recently as in 2003, for example, the CEO of defendant GlaxoSmithKline (“GSK”) denied any benefit from spread manipulation. In a conversation with shareholders GSK CEO J.P. Garnier stated that GSK “[has] never benefited from the spread becoming bigger or smaller.” Garnier stated that the reimbursement system “has a big loophole and can create confusion. We don’t like it one bit.” This was deliberately and entirely false as evidenced by the GSK spreads across the GSK product line (brand and generic alike) set forth in Exhibit B-19 hereto. GSK and its constituent predecessors Glaxo Wellcome and SmithKline Beecham long competed on spread and benefited from the increased market share permitted by the incentives the spread created.

**ANSWER:** Chiron denies the allegations in paragraph 24 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has “cause[d] false and inflated published reimbursement prices to issue.” Chiron further denies the characterization of “spread” in paragraph 24. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

25. As stated, Defendants create, inflate, manipulate and market the spread for both brand name and generic drugs. With generic drugs, direct competition among bioequivalents provides an obvious motive to increase the spread. With brands, creating incentives for formulary placement, as noted in the Geri-Med example, provides the same obvious motive. In both scenarios, Defendants compete on reimbursement and profit rather than cost.

**ANSWER:** Chiron denies the allegations in paragraph 25 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has “create[d], inflate[d], manipulate[d] and market[ed] the spread for both brand name and generic drugs.” Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

26. There is on average more divergence between the actual price and the AWP for generic drugs than there is for brand name drugs. A 2002 government report analyzing 1999 data found that pharmacists paid on average only 34.1% of AWP for generic drugs. For brand name drugs pharmacists paid on average only 78.2% of AWP. *See* Department of Health and Human Services, Office of Inspector General of the (“HHS OIG”), Medicaid Pharmacy-

Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (Sept. 16, 2002) (A-06-02-00041).

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 26 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied. Chiron respectfully refers the Court to Department of Health and Human Services, Office of Inspector General, “Medicaid Pharmacy-Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products” (Sept. 16, 2002) (A-06-02-00041) for a full and complete reading of its contents.

27. On December 7, 2004, the House Subcommittee of Oversight and Investigation of the Commerce and Energy Committee conducted a hearing on “Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much.” In his opening remarks, Chairman Joe Barton (R-TX) stated:

Data obtained by the committee from five of the largest retail pharmacy chains reveals that during the period of July 1, 2002 to June 20, 2003, the average acquisition costs for seven widely prescribed generic drugs was 22 cents, while the average Medicaid reimbursement just for those drugs alone was 56 cents, more than double the cost . . . .

Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm. on Oversight and Investigations, 108th Cong., December 7, 2004 (hereinafter “House Hearing”) Tr. at 3-4, 5 (statement of Joe Barton, Chairman, House Subcomm. on Oversight and Investigations).

**ANSWER:** Chiron respectfully refers the Court to the document titled “Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm. on Oversight and Investigations,” No. 108-126, at 5 (2004), referenced in paragraph 27 the Complaint, for its content, but denies any characterization thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 of the Complaint and therefore denies the same and demands strict proof thereof.

28. It has only recently become clear that these OIG, Congressional and other estimates of the extent of defendants' intentional AWP inflation were grossly understated—both as to generic and brand drug spreads—as the data set forth in the Exhibits B hereto demonstrate. Thus, it has only recently become clear that States' efforts to estimate EAC through a reimbursement formula that discounted 10, 12 or 15 percent off AWP were ineffective given the extent of defendants' fraud.

**ANSWER:** Chiron denies the allegations in paragraph 28 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has engaged in “intentional AWP inflation” or “fraud.” Chiron further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

29. No government report has ever addressed the falsity of WAC. Only through extensive investigation have the Counties learned that the WACs defendants reported or caused to be reported are false and inflated as alleged herein. Indeed, the fact that State Medicaid reimbursement formulas have historically been either [WAC + a certain %] or [AWP- a certain %] reveals the traditional belief in the reliability of WAC. Under either a “WAC plus” or “AWP minus” formula, the States were endeavoring to approximate EAC. Defendants' unlawful and undisclosed manipulation of the price reporting system as a whole has rendered States' efforts in this regard futile. And, as stated above, the publication of a false WAC leads to the publication of a false AWP.

**ANSWER:** Chiron denies the allegations in paragraph 29 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has “reported or caused to be reported [] false and inflated” WACs or engaged in any “unlawful and undisclosed manipulation of the price reporting system.” Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

30. Similarly, through their own extensive investigation the Counties have learned that defendants' pricing misconduct has caused the false and inflated FULs to issue. The Counties' investigation has revealed numerous examples where defendants' failures to report accurate prices for particular multi-source drugs have resulted in inflated FULs to be set resulting in substantial overpayments to the County Medicaid programs. *See* Exhibit B.

**ANSWER:** Chiron denies the allegations in paragraph 30 of the Complaint and Exhibit B attached thereto as to Chiron and demands strict proof thereof. Chiron specifically denies that it has engaged in any "pricing misconduct." Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Complaint and Exhibit B attached thereto as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

31. The second component of County Medicaid Programs' prescription drug costs concerns the federally mandated rebate that drug manufacturers are required to pay based on price information provided quarterly by the manufacturers. 42 U.S.C. § 1396r-8. The rebate for brand name drugs (defined as "single source drugs" or "innovator multiple source drugs") is the lesser of the difference between the Best Price and the Average Manufacturer's Price ("AMP")<sup>3</sup> or 15% of AMP. Best Price is the lowest price paid by any purchaser. "Wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the United States," with certain exclusions. AMP is the average price paid to the manufacturer by wholesalers after any prompt-pay discounts (typically 2%). *See* 42 U.S.C. § 1396r-8(c)(1)(C) (defining Best Price); 42 U.S.C. § 1396r-8(k)(1) (defining AMP). The lower the Best Price for a particular drug, the greater the rebate will be.

**ANSWER:** To the extent the allegations in paragraph 31 of the Complaint or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8; 42 U.S.C. § 1396r-8(c)(1)(C); 42 U.S.C. § 1396r-8(c)(3); 42 U.S.C. § 1396r-8(k)(1); and, N.Y. Soc. Serv. L. § 367 (a)(7)(d) for a full and complete reading of their provisions. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 of the Complaint or its footnote and therefore denies the same and

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<sup>3</sup> The rebate for other drugs is 11.1% of AMP. 42 U.S.C. § 1396r-8(c)(3); N.Y. Soc. Serv. L. § 367 (a)(7)(d).

demands strict proof thereof, except Chiron admits that it pays Medicaid rebates as required by law.

32. Defendants unlawfully reduce the amounts of rebates they pay for brand name drugs by omitting from their computations of Best Price statutorily and contractually required information. For example, defendants omit from their rebate calculations, cash payments, free goods, bundling of other free drugs, tying arrangements that are retroactive rebates, in-kind services, routine discounts (such as volume discounts, and the customary prompt pay discount), chargebacks, rebates, free samples and other off-invoice transactions and inducements offered to create market share and demand for their products.

**ANSWER:** Chiron denies the allegations in paragraph 32 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

33. Defendants, including Merck for its drug Pepcid and TAP for its drug Prevacid (to select two examples), make unlawful use of the so-called “nominal price” exception by omitting certain deeply discounted commercial sales from their Best Price calculation on the grounds that such fall within “nominal price.” The nominal price exception, however, is intended to apply to non-commercial sales.<sup>4</sup>

**ANSWER:** Chiron denies the allegations in paragraph 33 of the Complaint and its footnote as to Chiron and demands strict proof thereof. Chiron specifically denies that it has “abused” any Medicaid statute. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint and its footnote as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 33 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

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<sup>4</sup> The Medicaid statute permits pharmaceutical manufacturers to exclude from their Best Price calculations drugs with prices less than 10% of AMP. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). This exception permits drug manufacturers to continue to sell drugs at nominal prices *to entities serving the public good* without including those sales in their Best Price calculations (and therefore without causing defendants to pay higher rebates). However, certain manufacturers have abused the exception to hide commercial discounts.

Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III) for a full and complete reading of its provisions.

34. A 2001 report issued by the Department of Health and Human Services (“HHS”) found that many manufacturers had excluded from their Best Price calculations the discounted prices paid by HMOs, which were as much as 75 percent below the reported Best Price. *See* Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations, HHS Office of the Inspector General (Mar. 27, 2001).

**ANSWER:** Chiron denies the allegations in paragraph 34 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 34 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied. Chiron respectfully refers the Court to “Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations,” Department of Health and Human Services, Office of the Inspector General (Mar. 27, 2001) for a full and complete reading of its contents.

35. In 2003, two defendants herein, Bayer and GSK, agreed to pay \$346 million to resolve allegations that they defrauded Medicaid and Medicare by engaging in a scheme known as “lick and stick,” wherein they relabeled their products before selling them to Kaiser Permanente Medical Care Program (the nation’s largest HMO) at deep discounts, in order to exclude these discount-priced sales in computing and reporting their Best Prices.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 of the Complaint and therefore denies the same and demands strict proof thereof.

36. Numerous federal criminal and civil prosecutions illustrate that fraud with respect to both components of Medicaid pricing is pervasive among defendants. Defendant Abbott is paying \$621 million in criminal and civil penalties for defrauding Medicare and Medicaid and has affirmatively acknowledged its involvement in the fraud. Defendant Bristol Myers is under investigation in connection with its pricing practices for drugs covered by Medicare and Medicaid. Defendant AstraZeneca paid \$355 million to settle federal fraud charges that it

induced doctors to falsely bill Medicare and Medicaid. Defendant Schering-Plough has agreed to pay nearly \$350 million in fines and damages, and to plead guilty to criminal charges that it defrauded Medicaid. Defendant TAP Pharmaceuticals paid \$875 million in connection with its fraudulent pricing practices respecting Lupron. Defendant Warrick paid \$27 million to the state of Texas to resolve allegations that it reported fraudulent price information to Medicaid. Defendant Dey paid \$18 million to settle similar claims of defrauding Medicaid in Texas. *See* Exhibit D (detailing investigations and lawsuits against defendants named herein for unlawfully inflating Medicaid prices based on AWP and understating the true amounts of Medicaid rebates owed).

**ANSWER:** Chiron denies the allegations in paragraph 36 of the Complaint as to Chiron and demands strict proof thereof, except Chiron admits that Plaintiffs' Exhibit D is correct to the extent that Exhibit D states Chiron has been sued by the State of Illinois. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

37. As a result of defendants' fraudulent and illegal manipulation of drug prices, defendants have reaped billions of dollars in illegal profits. By this action, the Counties seek (1) recovery of the excessive Medicaid pharmacy costs paid by the City, the Counties, the State of New York, and the United States as a result of defendants' intentional misconduct; (2) an accounting for and payment of the full amount of rebates owed; (3) disgorgement of defendants' unlawful profits; (4) punitive damages; and (5) entry of an order directing defendants henceforth to report accurate wholesale price information, AMPs and Best Prices and pay correct rebates in compliance with federal and state statutes.

**ANSWER:** To the extent numbered paragraph 37 of the Complaint states conclusions of law, no response is required. To the extent a response is required, Chiron admits that the Counties purport to bring this lawsuit to recover damages and obtain the forms of relief as set forth herein, but denies there is any basis for them to do so and denies that they are entitled to any relief. Chiron denies the remaining allegations in paragraph 37 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it has been involved in any "fraudulent and illegal manipulation of drug prices." Chiron is without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 37 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO JURISDICTION AND VENUE**

38. Plaintiffs claim violations of, *inter alia*, the Social Security Act, 42 U.S.C. § 1396 *et seq.*, N.Y. Social Services Law §§ 145-b and 367a, and N.Y. General Business Law § 349, and breach of contract, unjust enrichment, and common law fraud.

**ANSWER:** Chiron admits that Plaintiffs claim violations of, *inter alia*, the Social Security Act, 42 U.S.C. § 1396 *et seq.*, N.Y. Social Services Law §§ 145-b and 367a, and N.Y. General Business Law § 349, and breach of contract, unjust enrichment, and common law fraud, but Chiron denies there is any basis for them to do so and denies that they are entitled to any relief. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 38 of the Complaint and therefore denies the same and demands strict proof thereof.

39. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations of the Social Security Act, 42 U.S.C. § 1396 *et seq.* and breach of the federal Medicaid Rebate Contract, 42 U.S.C. § 1396r-8. This Court has supplemental jurisdiction over the Counties' state law claims pursuant to 28 U.S.C. § 1367.

**ANSWER:** The allegations set forth in paragraph 39 of the Complaint state jurisdictional allegations and legal conclusions to which no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 39 of the Complaint and demands strict proof thereof, except admits that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

40. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) because each of the captioned matters has been transferred by the Judicial Panel on Multi District Litigation to this district for pre-trial purposes pursuant to 28 U.S.C. § 1407. The City and Counties originally filed cases in each of their respective federal district courts as noted in the caption. Venue in such courts is proper because defendants do business and are qualified to do

business in such districts; certain acts giving rise to the claims asserted in this complaint occurred within such districts; and the illegal actions of defendants, as alleged in this complaint, caused damage to plaintiffs within such districts.

**ANSWER:** The allegations set forth in paragraph 40 of the Complaint state jurisdictional allegations and legal conclusions to which no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 40 of the Complaint, except admits that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

#### **ANSWER TO PARTIES**

41. The City of New York and every County represented by Kirby McInerney & Squire, LLP (i.e., all Counties except Nassau) is a municipal corporation organized pursuant to the laws of the State of New York. By statute, each plaintiff pays 25% of its County Medicaid Program's Medicaid prescription drug costs. N.Y. Soc. Serv. L. §§ 367-a and 368-a. Each plaintiff has paid for the subject drugs manufactured and marketed by each defendant.

**ANSWER:** To the extent paragraph 41 of the Complaint states conclusions of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 41 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. §§ 367-a and 368-a for a full and complete reading of their provisions.

42. Plaintiff, the County of Nassau, New York is a municipal corporation organized pursuant to the laws of New York State. Nassau County maintains its principal place of business at One West Street, Mineola, New York. The County is statutorily required to pay 25% of its County Medicaid program's Medicaid prescription drug costs to the State for reimbursement of the State's expenditures under N.Y. Soc. Serv. Law §§ 367-68. Plaintiff has paid for the subject drugs manufactured and marketed by each defendant.

**ANSWER:** To the extent paragraph 42 of the Complaint states conclusions of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 42 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. Law §§ 367-68 for a full and complete reading of their provisions.

42A. Plaintiff, the County of Orange, New York is a municipal corporation organized pursuant to the laws of New York State. Orange County maintains its principal place of business at 255 Main Street, Goshen, New York. The County is statutorily required to pay 25% of its County Medicaid program's Medicaid prescription drug costs to the State for reimbursement of the State's expenditures under N.Y. Soc. Serv. Law §§ 367-68. Plaintiff has paid for the subject drugs manufactured and marketed by each defendant.

**ANSWER:** To the extent paragraph 42A of the Complaint states conclusions of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42A of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 42A refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. Law §§ 367-68 for a full and complete reading of their provisions.

43. Each plaintiff brings suit against each defendant named herein with the following exceptions: The City of New York asserts no claims against the Pfizer Group defendants. The County of Onondaga asserts no claims against the Bristol Myers Squibb defendants. The County of Suffolk, in this complaint, asserts claims only against Alpharma, Alpha Therapeutics, Dey, Endo, Ethex, Hoffman-LaRoche, The King Group, The Mylan Group, Organon and Serono.<sup>5</sup>

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<sup>5</sup> Suffolk has already asserted claims against the remaining defendants named herein. *See* Suffolk's Revised Amended Complaint filed August 3, 2003. Those claims have been sustained in part and dismissed in part. Suffolk presently will file a motion for leave to join in this Consolidated Complaint with respect to those defendants.

**ANSWER:** Chiron admits that Plaintiffs purport to sue certain defendants with certain exceptions, refers to Case Management Order No. 33, dated September 14, 2007, ¶¶ 1, 3 for a list of which plaintiffs are suing which defendants, and states that Chiron is named in eleven of the forty-two Consolidated Counties (Chemung, Columbia, Cortland, Dutchess, Essex, Lewis, Ontario, Orleans, Schuyler, Seneca, and Wyoming), and in Nassau County. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 43 and its footnote and therefore denies the same and demands strict proof thereof.

44. Defendants are manufacturers and sellers of prescription drugs. Each defendant conducts extensive business in the State of New York, including in the City of New York and in the Counties. Each defendant manufactures, markets and sells prescription drugs with false and inflated wholesale prices that are paid for by the County Medicaid Programs.

**ANSWER:** Chiron admits that it manufactures and sells prescription drugs and that it transacts business in the State and City of New York. Chiron denies the remaining allegations in paragraph 44 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it “manufactures, markets and sells prescription drugs with false and inflated wholesale prices.” Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**Paragraphs 45-55 (Allegations concerning various other Defendants)**

**ANSWER:** The allegations in paragraphs 45-55 are directed to other defendants and require no response from Chiron. To the extent a response is deemed required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 45-55 of the Complaint and therefore denies the same and demands strict proof thereof.

56. Defendant **CHIRON CORPORATION** is a Delaware Corporation engaged in the business of manufacturing and selling pharmaceuticals. Chiron Corporation's principal place of business is located at 4560 Horton St., Emeryville, CA 94608-2916. Chiron Corporation is also being sued for the conduct of its subsidiaries, divisions and predecessor corporations, including but not limited to Cetus Oncology Corp. These entities are referred to herein as "Chiron".

**ANSWER:** Chiron admits that it is a corporation organized under the laws of Delaware, but states that its principal place of business is 350 Massachusetts Avenue, Cambridge, Massachusetts 02139. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 56 and therefore denies the same and demands strict proof thereof.

**Paragraphs 57-84 (Allegations concerning various other Defendants)**

**ANSWER:** The allegations in paragraphs 57-84 of the Complaint are directed to other defendants and require no response from Chiron. To the extent a response is deemed required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 57-84 of the Complaint and therefore denies the same and demands strict proof thereof.

**ANSWER TO AS YET UNNAMED CO-CONSPIRATORS AND DOE DEFENDANTS**

85. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, presently unknown to the Counties and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted, or participated with defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by the Counties.

**ANSWER:** The allegations in paragraphs 85 of the Complaint are directed to unknown defendants and require no response from Chiron. To the extent a response is deemed required, Chiron denies the allegations in paragraph 85 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it was involved any conspiracy

related to drug pricing with either named or unknown defendants, or that it has engaged in any “wrongful acts” related to drug pricing. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

86. Except as described herein, the Counties are, as yet, ignorant of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-100 inclusive and, therefore, sue these defendants by such fictitious names. The Counties will amend this Complaint to allege the true names and capacities of the Doe defendants when ascertained.

**ANSWER:** The allegations set forth in paragraph 86 of the Complaint explain the nature of the Counties’ ignorance and future action to be taken by the Counties to which no response is required. In addition, the allegations in paragraph 86 are directed to unknown defendants and require no response from Chiron. To the extent a response is deemed required, Chiron denies the allegations in paragraph 86 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

87. Defendants unknown at this time may include independent pharmacies, dispensers, and other Pharmacy Providers who prescribed drugs and received inflated Medicaid reimbursements and engaged in fraudulent billing practices, as well as various other persons, wholesalers, publishers, partnerships, sole proprietors, firms, corporations and individuals that may have participated as co-conspirators with defendants in the offenses alleged in this complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.

**ANSWER:** The allegations in paragraph 87 of the Complaint are directed to unknown defendants and require no response from Chiron. To the extent a response is deemed required, Chiron denies the allegations in paragraph 87 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief

as to the truth of the allegations in paragraph 87 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

88. Each of the defendants designated herein as a Doe defendant is legally responsible in some manner for the unlawful acts referred to herein. Plaintiffs will seek leave of Court if necessary to amend this Complaint to reflect the true names and capacities of the defendants designated herein as Does when such identities become known.

**ANSWER:** To the extent paragraph 88 of the Complaint states conclusions of law, no response is required. In addition, the allegations in paragraph 88 are directed to unknown defendants and require no response from Chiron. To the extent a response is deemed required, Chiron denies the allegations in paragraph 88 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO ALLEGATIONS APPLICABLE TO ALL DEFENDANTS**

89. Medicaid was established by Title XIX of the Federal Social Security Act (the “Act”), 42 U.S.C. §§ 1396 *et seq.* (the “Medicaid Program”). The Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers, such as defendants, participating in the Medicaid Program.

**ANSWER:** To the extent paragraph 89 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that Medicaid was established by Title XIX of the Social Security Act, and states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 89 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. §§ 1396 *et seq.* for a full and complete reading of their provisions.

90. State participation in Medicaid is voluntary, but once a state agrees to participate, as New York has (*see* N.Y. Social Services Law § 363 *et seq.*), the state must comply with all federal statutory requirements. The Medicaid plan proposed by each state must be approved by the federal government. *See* 42 U.S.C. § 1396a(a) and (b). New York State's Medicaid plan has been expressly approved by the federal government. 42 C.F.R. § 433.32, at 79-29, 42 C.F.R. § 433.33, at 80-84.

**ANSWER:** To the extent paragraph 90 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 90 of the Complaint and therefore denies the same and demands strict proof thereof, except Chiron admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in paragraph 90 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to the statutes cited by Plaintiffs in paragraph 90 for a full and complete reading of their provisions but states that it lacks knowledge or information as to what 42 C.F.R. § 433.32, at 79-29 and 42 C.F.R. § 433.33, at 80-84 refer.

91. New York State's Medicaid plan requires that local social service districts, such as the Counties, pay one half of the district's costs for drugs covered by Medicaid, after first deducting the federal share. N.Y. Social Services Law § 368-a. The federal share is generally 50 percent of the cost, 42 U.S.C. § 1396(d)(b), leaving the remaining 50 percent to be split equally between the State and the Counties.

**ANSWER:** To the extent paragraph 91 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 91 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 91 of the Complaint refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

Chiron respectfully refers the Court to N.Y. Social Services Law § 368-a and 42 U.S.C. § 1396(d)(b) for a full and complete reading of their provisions.

92. Federal Medicaid law requires states and localities to seek recovery of the full amount of any overcharge to the Medicaid program, including the federal and state shares of such overcharges. 42 U.S.C. § 1396a(a)(25)(A) & (B); 42 U.S.C. § 1396b(d)(3)(A). New York law implements these federal statutory requirements by providing treble damages for any knowing overcharge of the Medicaid program, and further providing to “the local social services district or the state” a cause of action for recovery of such damages. N.Y. Soc. Serv. L. § 145-b(2). Under the New York statute, “[a]mounts collected pursuant to a judgment under this section shall be apportioned between the local social services district and the state.” *Id.*

**ANSWER:** To the extent paragraph 92 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 92 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 92 of the Complaint refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396a(a)(25)(A) & (B); 42 U.S.C. § 1396b(d)(3)(A); and N.Y. Soc. Serv. L. § 145-b(2) for a full and complete reading of their provisions.

93. As stated, New York State Statute provides that, in general, if CMS has established a FUL for a particular multi-source drug, New York Medicaid will reimburse Pharmacy Providers for that drug based on the FUL. N.Y. Soc. Serv. L. § 367-a(9)(b)(i).

**ANSWER:** To the extent paragraph 93 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 93 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 93 of the Complaint refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9)(b)(i) for a full and complete reading of its provisions.

94. The one exception to the above rule is that even where a FUL is in place, “if a qualified prescriber certifies ‘brand medically necessary’ or ‘brand necessary’ in his or her own handwriting directly on the face of a prescription for a multiple source drug for which a specific upper limit of reimbursement has been established by the federal agency, in addition to writing ‘d a w’ in the box provided for such purpose on the prescription form, reimbursement for that innovator multisource drug will be made based on AWP.” N.Y.Soc. Serv.L. § 367-a(9)(c).

**ANSWER:** To the extent paragraph 94 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 94 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 94 of the Complaint refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y.Soc. Serv.L. § 367-a(9)(c) for a full and complete reading of its provisions.

95. If no FUL is in place for particular drug, New York Statute provides for reimbursement at estimated acquisition cost or EAC. New York Statute defines EAC at AWP less a percentage discount. N.Y. Soc. Serv. L. § 367-a(9)(b)(ii).

**ANSWER:** To the extent paragraph 95 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 95 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 95 of the Complaint refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9)(b)(ii) for a full and complete reading of its provisions.

96. Prior to April 15, 2003, the formula was AWP minus 10%. From May 15, 2003 to April 1, 2004, the formula was AWP minus 12%. N.Y. Soc. Serv. L. § 367-a(9)(b)(ii)<sup>6</sup>; *see* N.Y. Laws 2003, Ch. 62, Part Z2 (decreasing reimbursement from AWP minus 10% to AWP minus 12%).

**ANSWER:** To the extent paragraph 96 of the Complaint and its footnote state conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 96 and its footnote and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 96 of the Complaint and its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9)(b)(ii) and N.Y. Laws 2003, Ch. 62, Part Z2 for a full and complete reading of their provisions.

97. In 2004, N.Y. Soc. Serv. L. § 367-a(9) was amended, effective April 1, 2004, to provide that brand name drugs are reimbursed through Medicaid at the rate of AWP minus 12.75%<sup>7</sup> and generic drugs for which no FUL has been established are reimbursed at AWP minus 16% or at a maximum price determined by the New York State Commissioner of Health using “a similar methodology as that utilized by the Centers for Medicare and Medicaid Services in establishing the federal upper payment limit.” N.Y. Soc. Serv. L. § 367-a(9)(e) and Laws 2004, Ch. 58, Part C, § 36.

**ANSWER:** To the extent paragraph 97 of the Complaint and its footnote state conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 and its footnote and therefore denies the

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<sup>6</sup> The alternative measure of reimbursement for brand name drugs set forth in subsection (ii), the “usual and customary price charged to the general public,” is not used because the necessary data are not available. This alternative measure has been retained in the 2004 amendment.

<sup>7</sup> The 2004 amendment creates one exception to the reimbursement formula: “specialized HIV pharmacies”, as defined by N.Y. Soc. Serv. L. §367-a(9)(f), are reimbursed for all drugs without FULs at AWP minus 12%. N.Y. Soc. Serv. L. §367-a(9)(b)(ii).

same and demands strict proof thereof. To the extent the allegations in paragraph 97 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9)(b)(ii), N.Y. Soc. Serv. L. § 367-a(9)(e), and Laws 2004, Ch. 58, Part C, § 36 for a full and complete reading of their provisions.

98. In addition, New York law has at all relevant times provided for a dispensing fee of between \$3.50 and \$4.50 to be added to all reimbursements. N.Y. Soc. Serv. L. § 367-a(9)(d).

**ANSWER:** To the extent paragraph 98 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 98 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 98 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(9)(d) for a full and complete reading of its provisions.

99. The Medicaid reimbursements at issue in this litigation are those made on the basis of AWP and FUL. Every drug listed in Exhibit B to this complaint, regardless what type of drug it is or what form it takes (i.e., tablet, vial, inhalant, injectible, syringe, solution, etc) *or whether it could also be identified as or labeled “physician administered”* has been reimbursed by New York Medicaid based on AWP or FUL.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 99 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 99 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

100. By way of background, every prescription drug in the United States is assigned a National Drug Code (“NDC codes”), also known as a formulary code. The United States Food

and Drug Administration publishes such codes for each of the various dosages and packagings of each drug.

**ANSWER:** Chiron admits that there is a unique NDC number for each dosage and package size for each drug sold by Chiron. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 100 of the Complaint and therefore denies the same and demands strict proof thereof.

101. While New York has at all times relevant hereto maintained an open formulary, since at least 1991, the New York State Department of Health has maintained a “List of Medicaid Reimbursable Drugs”. This List identifies - by NDC - all drugs for which New York Medicaid will reimburse Pharmacy Providers when they submit a claim for reimbursement. It is, in fact, a list of every Medicaid covered drug.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 101 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 101 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

102. Every drug listed in Exhibit B to this Complaint has appeared on this List of Medicaid Reimbursable Drugs.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 102 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 102 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

103. The List of Medicaid Reimbursable Drugs sets forth, for each NDC, the “MRA Cost” (or Maximum Reimbursement Amount Cost) that New York Medicaid will pay.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 103 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 103 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

104. At all times between 1992 and September 5, 2006, the MRA Cost has been based upon either the drug's reported AWP or any FUL that was in place.<sup>8</sup>

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104 of the Complaint and its footnote and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 104 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

105. Any licensed Pharmacy Provider enrolled in the New York Medicaid program who submits a claim for any drug on the List of Medicaid Reimbursable Drugs is reimbursed at the MRA Cost. Since the MRA cost is based on AWP or FUL, this means that between 1992 and September 5, 2006, the Pharmacy Provider was reimbursed based on AWP or FUL when the Provider submitted a claim for any drug on the List of Medicaid Reimbursable Drugs.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 105 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

106. Every drug listed in Exhibit B to this complaint has appeared on the List of Medicaid Reimbursable Drugs and was reimbursed based on AWP or FUL when the claim for that drug was submitted by a Pharmacy Provider.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 106 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

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<sup>8</sup> From September 5, 2006 to the present, the MRA Cost has been based upon either the drug's reported AWP, any FUL that has been in place or the newly-implemented New York State Maximum Allowable Cost (SMAC).

107. Pharmacy Providers are all forms of licensed pharmacies enrolled in the New York Medicaid Program. This includes all forms of retail pharmacies, chain pharmacies, specialty pharmacies, home infusion companies, long term care pharmacies, out-patient hospital pharmacies, out-patient clinic pharmacies or any other licensed and enrolled Pharmacy Provider.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107 of the Complaint and therefore denies the same and demands strict proof thereof.

108. Pharmacy Providers have routinely submitted claims for all of the drugs listed in Exhibit B, be that drug a tablet, syringe, vial, inhalant, injectible drug or otherwise. And, when a Pharmacy Provider submits such claim, that Pharmacy Provider is reimbursed based on AWP or FUL.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 108 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

109. *The type or form of of drug, i.e., tablet, syringe, vial, inhalant, injectible drug or otherwise, has no relevance whatsoever in the New York Medicaid statutory scheme. The label "Physician Administered Drug" has no meaning in the New York Medicaid statutory scheme.* Thus, if a home infusion pharmacy, one type of Pharmacy Provider, submits a claim for an injectible drug on the List of Medicaid Reimbursable Drugs, that home infusion pharmacy is reimbursed based on AWP or FUL.

**ANSWER:** To the extent paragraph 109 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 109 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

110. Between 1997-2004 alone, New York Medicaid has reimbursed Pharmacy Providers based on AWP or FUL for the injectibles, syringes, inhalants and vials listed in the Exhibits hereto in an amount that exceeds \$2.4 billion.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the Complaint and therefore denies the same and demands strict proof thereof.

111. New York Medicaid only reimburses for drugs based on actual (or invoice) cost when the drug is “provided by a medical practitioner and claimed separately by the practioner”. N.Y. Soc. Serv. Law § 367-a(9)(a). Medicaid practitioners are not Pharmacy Providers under New York Medicaid; Pharmacy Providers are not medical practitioners.

**ANSWER:** To the extent paragraph 111 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 111 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to N.Y. Soc. Serv. Law § 367-a(9)(a) for a full and complete reading of its provisions.

112. AWP's and FUL's are published and reported by non-party publishing compendia such as First Data Bank's Blue Book (“FDB”) based on pricing information supplied by defendant drug manufacturers. At all times relevant hereto, New York has used FDB as its source for FUL's and AWP's.

**ANSWER:** Chiron admits that independent third-party pricing compendia such as First DataBank publish AWP's and FUL's, but denies that Chiron has any control over the information that First DataBank, an independent third-party, publishes. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations

in paragraph 112 of the Complaint and therefore denies the same and demands strict proof thereof.

113. States must rely on AWP and FUL as proxies for EAC in large part because defendants purposefully and fraudulently conceal their true prices claiming they are proprietary trade secrets. Even at the time when the Medicaid rebate provision was enacted, the manufacturers made sure that pricing information would not be disclosed to the states. As Representative Henry Waxman explained during the December 2004 House Committee on Energy and Commerce hearings, or Medicaid pricing practices.

the drug industry was powerful, and they succeeded in securing a provision in the basic legislation that kept the Best Price and the AMP information a secret. Can you imagine that? The federal government knew this information, but we kept it a secret from the states. This has proved to be a costly error. Without this crucial piece of information, states who were, after all, responsible establishing the reimbursement rate for prescription drugs could not set their reimbursement rates appropriately. As a result, [the states] continued to rely on the average wholesale price minus the arbitrary amount because they did not have the information needed to set a more appropriate reimbursement rate.

*House Hearing Tr. at 23.*

**ANSWER:** Chiron denies the allegations in paragraph 113 of the Complaint as they pertain to Chiron and demands strict proof thereof. Chiron specifically denies that it has fraudulently conceal[ed]” the “true prices” of its drugs by “claiming they are proprietary trade secrets.” Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 113 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied. Chiron respectfully refers the Court to the House Hearing Transcript to which Plaintiffs referred in paragraph 113 of the Complaint for a full and complete reading of its contents.

114. The federal government has emphasized the importance of accurate reported prices. In its April 2003 report, “Compliance Program Guidance for Pharmaceutical

Manufacturers,” the HHS OIG reaffirmed that the “government sets reimbursement with the expectation that the data provided are complete and accurate.” The OIG made clear that “manufacturers reported prices” must be meaningful figures that are tethered to actual prices:

Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Off. of Inspector Gen., Dep’t of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers*, at 12 (2003). Defendants routinely and consistently violate this. They sell the vast majority of their drugs at prices that bear little or no relation to the reimbursement prices they report to the publishing compendia.

**ANSWER:** Chiron denies the allegations in paragraph 114 of the Complaint as to Chiron and demands strict proof thereof, except admits that Off. of Inspector Gen., Dep’t of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers*, at 12 (2003) contains a section that discusses “manufacturers’ reported prices.” Chiron further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to Off. of Inspector Gen., Dep’t of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers* (2003) for a full and complete reading of its contents.

115. The OIG has rejected the notion that purposeful manipulation of reimbursement prices generally, and AWP in particular, is a lawful practice:

The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer’s profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. **In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.**

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. **The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or

guaranteeing a certain profit or spread in exchange for the purchase of a product.

*Id.* at 26-27 (2003) [emphases added].

**ANSWER:** Chiron denies the allegations in paragraph 115 of the Complaint as to Chiron and demands strict proof thereof, except Chiron admits that the Off. of Inspector Gen., Dep't of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers*, at 26-27 (2003) contains a section entitled "Average Wholesale Price" that discusses AWP, and states that Plaintiffs accurately quote a select portion from pages 26-27 of the Off. of Inspector Gen., Dep't of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers* (2003). Chiron further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to Off. of Inspector Gen., Dep't of Health and Human Services, *Compliance Program Guidance for Pharmaceutical Manufacturers* (2003) for a full and complete reading of its contents.

116. The second component of the price that Medicaid pays for prescription drugs is determined by the federally mandated rebate provision. Under the Medicaid rebate provision, 42 U.S.C. § 1396r-8, a manufacturer of a drug that wishes to have its products paid for by Medicaid must enter into a rebate agreement with the Secretary of Health and Human Services.

**ANSWER:** To the extent paragraph 116 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8 contains certain provisions regarding the circumstances pursuant to which a manufacturer of a drug must enter into a Medicaid rebate agreement with the

Secretary of Health and Human Services. Chiron further states that the rebate provision speaks for itself, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

117. The rebate for brand-name drugs (defined as “single source drugs” or “innovator multiple source drugs”) is the difference between the AMP and the Best Price, or 15% of the AMP, whichever is greater. 42 U.S.C. §§ 1396r-8(c)(1) – (2); N.Y. Soc. Serv. L. § 367 (a)(7)(d). Thus, the lower the Best Price, the greater the rebate.

**ANSWER:** To the extent paragraph 117 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that the statutes cited in paragraph 117 define the methodology to calculate rebates on brand drugs. Chiron denies the remaining allegations in paragraph 117 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. §§ 1396r-8(c)(1) – (2) and N.Y. Soc. Serv. L. § 367 (a)(7)(d) for a full and complete reading of their provisions.

118. The statute requires each manufacturer of single source or brand name innovator drugs to report to Medicaid its Best Price and its AMP and to pay rebates to state Medicaid programs based on its own accurate determination of Best Price and AMP. 42 U.S.C. § 1396r-8(b)(1)(A).<sup>9</sup>

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<sup>9</sup> The rebate for other drugs is 11.1% of AMP. 42 U.S.C. § 1396r-8(c)(3); N.Y. Soc. Serv. L. § 367 (a)(7)(d).

**ANSWER:** To the extent paragraph 118 of the Complaint and its footnote state conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8 contains certain provisions regarding the reporting of pricing information by manufacturers of single source or brand name innovator drugs and the payment of rebates to state Medicaid programs, and respectfully refers the Court to 42 U.S.C. § 1396r-8(b)(1)(A); 42 U.S.C. § 1396r-8(c)(3); and, N.Y. Soc. Serv. L. § 367 (a)(7)(d) for a full and complete reading of their provisions. Chiron denies the remaining allegations in paragraph 118 and its footnote as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

119. Where the cost of a drug has outpaced the increase in the consumer price index over a period of time, the Medicaid rebate provision requires each drug manufacturer to pay an additional rebate. 42 U.S.C. § 1396r-8(c)(2), [sic]

**ANSWER:** To the extent paragraph 119 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8(c)(2) contains certain provisions regarding the payment of additional Medicaid rebates, and respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(2) for a full and complete reading of the provisions of the law regarding the payment of additional Medicaid rebates. Chiron denies the remaining allegations in paragraph 119 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict

proof thereof. To the extent the allegations in paragraph 119 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

120. The Medicaid rebate provision contains precise specifications concerning how Best Price is to be calculated. It defines Best Price as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity in the United States,” with certain enumerated exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i).

**ANSWER:** To the extent paragraph 120 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8(c)(1)(C)(i) contains certain provisions regarding Best Price, and respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(1)(C)(i) for a full and complete reading of its provisions regarding Best Price. Chiron denies the remaining allegations in paragraph 120 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 120 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 120 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

121. After excluding the prices given to certain drug purchasers from the definition and including others explicitly, the Statute states:

the term “Best Price” –

- (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
- (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
- (III) shall not take into account prices that are merely nominal in amount.

42 U.S.C. § 1396r-8(c)(1)(C)(ii).

**ANSWER:** To the extent paragraph 121 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8(c)(1)(C)(ii) contains certain provisions regarding Best Price, and respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(1)(C)(ii) for a full and complete reading of its provisions regarding Best Price. Chiron denies the remaining allegations in paragraph 121 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 121 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

122. AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8(k)(1).

**ANSWER:** To the extent paragraph 122 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8(k)(1) contains certain provisions regarding AMP, and respectfully refers the Court to 42 U.S.C. § 1396r-8(k)(1) as it existed at the time Plaintiffs filed their initial Complaint in June 2005 for a full and complete reading of its provisions. Chiron denies the remaining allegations in paragraph 122 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the

allegations in paragraph 122 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

123. Congress passed the rebate provision expressly to help reduce state Medicaid drug expenditures. H.R. Rep. No. 101-881 at 96-8 (1990), U.S.C.C.A.N. 1990, 2017, 2108-2110.

**ANSWER:** To the extent paragraph 123 of the Complaint states conclusions or characterization of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 123 refer to statutes, regulations, or to the congressional record, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to H.R. Rep. No. 101-881 at 96-8 (1990), U.S.C.C.A.N. 1990, 2017, 2108-2110 for a full and complete reading of its contents.

124. New York Social Service Law § 367-a(7)(d) expressly incorporates the rebate requirements of 42 U.S.C. § 1396r-8 and provides that where a manufacturer has entered into a rebate agreement, as outlined above, reimbursement to the New York State Medicaid program shall be made only pursuant to the terms of that rebate agreement.

**ANSWER:** To the extent paragraph 124 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 124 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Service Law § 367-a(7)(d) and 42 U.S.C. § 1396r-8 for a full and complete reading of their provisions.

125. New York Social Service Law also requires that the State return to the local social service district, such as the Counties, the local district's *pro rata* share of any rebate received.

New York's Medicaid plan was approved expressly by the federal government. Each plaintiff here is within the class of entities for whose benefit the Medicaid rebate provision was enacted.

**ANSWER:** To the extent paragraph 125 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 125 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to the New York Social Service Law to which Plaintiffs referred in paragraph 125 for a full and complete reading of its relevant provisions.

126. To effectuate the purpose of the statute, manufacturers are required to report their Best Prices and AMPs to the Secretary of HHS, who is required to keep the information confidential. 42 U.S.C. §§ 1396r-8(b)(3)(A), (D).

**ANSWER:** To the extent paragraph 126 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. §§ 1396r-8 contains certain provisions regarding the reporting of pricing information to the Secretary of Health and Human Services and the confidentiality of such pricing information, and respectfully refers the Court to 42 U.S.C. §§ 1396r-8(b)(3)(A), (D) for a full and complete reading of their provisions. Chiron denies the remaining allegations in paragraph 126 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 126 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 126 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

127. The states are required to report to the manufacturers, as well as to HHS, the “information on the total number of units of each dosage strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period.” 42 U.S.C. § 1396r-8(b)(2).

**ANSWER:** To the extent paragraph 127 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. §§ 1396r-8 contains certain provisions regarding the reporting of information by the states to manufacturers and to the Secretary of Health and Human Services for drugs for which payment has been made, and respectfully refers the Court to 42 U.S.C. § 1396r-8(b)(2) for a full and complete reading of its provisions. Chiron denies the remaining allegations in paragraph 127 of the Complaint as to Chiron and demands strict proof thereof. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 127 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 127 refer to additional statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

128. The Secretary calculates the rebates according to the statutory formulas and reports to each state a Unit Rebate Amount (“URA”), which is “the amount calculated by the Health Care Financing Administration to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due.” The rebate then is paid to the state Medicaid program by the defendant drug manufacturer.

**ANSWER:** To the extent paragraph 128 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that it pays rebates to the State of New York and that these rebates lower the State of New York’s cost of prescription drugs for Medicaid patients. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128 of the Complaint and therefore denies the same and demands strict proof thereof.

129. States thus are provided with URAs, not the AMPs or Best Prices. *See* Brief of the United States as *Amicus Curiae* filed in *In re: Pharmaceutical Industry Average Wholesale Price Litigation* (No. 01-CV-12257-PBS) (MDL No. 1456 D. Mass.) at 15 (arguing that the federal rebate provision, 42 U.S.C. § 1396r-8, does not preempt state law fraud claims based on fraudulent reporting of rebate data) (hereinafter “*Amicus* brief”). Like HHS, States are also required to keep confidential the rebate-related information that they receive. 42 U.S.C. § 1396r-8(b)(3)(D).

**ANSWER:** To the extent paragraph 129 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 129 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 129 of the Complaint refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8(b)(3)(D) for a full and complete reading of its provisions.

130. The Secretary relies entirely on the manufacturers for Best Price and AMP data.

**ANSWER:** Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130 of the Complaint and therefore denies the same and demands strict proof thereof.

131. At all times, the manufacturers have ultimate responsibility to correctly calculate the rebate:

A State may, at its option, compute the total rebate anticipated, based on its own records, *but it shall remain the responsibility of the labeler* to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

Model Rebate Agreement, annexed hereto and incorporated herein, at I(n).

**ANSWER:** To the extent paragraph 131 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that Plaintiffs accurately quote a select portion of paragraph (n) under Section I of

the Model Rebate Agreement, which is attached to Plaintiffs' Complaint at Exhibit E, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron further states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 131 of the Complaint and therefore denies the same and demands strict proof thereof.

132. Each defendant and the Secretary of Health and Human Services "on behalf of the Department of Health and all States and the District of Columbia . . . which have a Medicaid State Plan approved under 42 U.S.C. § 1396a" has executed a Rebate Agreement that is in all material respects identical to the Model Rebate Agreement (Exhibit E).

**ANSWER:** To the extent paragraph 132 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that Plaintiffs accurately quote a select portion of the first paragraph before Section I of the Model Rebate Agreement, which is attached to Plaintiffs' Complaint at Exhibit E, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied, and that it has executed a Rebate Agreement similar to the Model Rebate Agreement attached at Exhibit E. Chiron further states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 132 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 132 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

133. While the Model Rebate Agreement largely tracks the statutory rebate provision, it also goes beyond it in some respects. The Model Rebate Agreement defines Best Price as "the lowest price at which the manufacturer sells . . . to any purchaser in the United States in any pricing structure." Model Rebate Agreement, at I(d).

**ANSWER:** To the extent paragraph 133 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required,

Chiron admits that Plaintiffs accurately quote a select portion of paragraph (d) under Section I of the Model Rebate Agreement, which is attached to Plaintiffs' Complaint at Exhibit E, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron further states that it is without knowledge or information sufficient to form a belief as to the truth of the remaininig allegations in paragraph 133 of the Complaint and therefore denies the same and demands strict proof thereof.

134. The Model Rebate Agreement provides also that "[f]or bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement." *Id.*, at I(d).

**ANSWER:** Chiron admits that Plaintiffs accurately quote a select portion of paragraph (d) under Section I of the Model Rebate Agreement, which is attached to Plaintiffs' Complaint at Exhibit E, except notes that the term "bundled sales" is capitalized in the rebate agreement, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaininig allegations in paragraph 134 of the Complaint and therefore denies the same and demands strict proof thereof.

135. Bundled discounts are defined in the Model Rebate Agreement as "the packaging of drugs of different types where the condition of rebate or discount is that more than one type of drug is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately." *Id.* at I(e).

**ANSWER:** Chiron admits that Plaintiffs accurately quote a select portion of paragraph (e) under Section I of the Model Rebate Agreement, which is attached to Plaintiffs' Complaint at Exhibit E, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 135 of the Complaint and therefore denies the same and demands strict proof thereof.

136. The Model Rebate Agreement defines “State Medicaid Agency” as “the agency designated by a state under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.” Model Rebate Agreement at I(bb).

**ANSWER:** Chiron admits that Plaintiffs accurately quote a select portion of paragraph (bb) under Section I of the Model Rebate Agreement, which is attached to Plaintiffs’ Complaint at Exhibit E, and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron notes, however, that “state” in the referenced quotation should be capitalized. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 136 of the Complaint and therefore denies the same and demands strict proof thereof.

137. Under New York law, the Counties are local social services districts within New York State. N.Y. Soc. Serv. L. §§ 56, 61-62. Within the State scheme, and subject to State supervision, the City and Counties play a significant role in administering the Medicaid program for the Counties’ residents. Each has its own fraud and overpayments unit, determines eligibility, and performs other important functions. Numerous Counties likewise engaged in these critical functions.

**ANSWER:** To the extent paragraph 137 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 137 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. §§ 56, 61-62 for a full and complete reading of their provisions.

138. The Medicaid Rebate statute further provides that “the State or local agency administering such plan will take all reasonable measures to ascertain the legal liability of third parties for any overcharges and submit to the Secretary of Health and Human Services a plan for pursuing such claims.” 42 U.S.C. § 1396a (a)(25)(A).

**ANSWER:** To the extent paragraph 138 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required,

Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 138 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396a (a)(25)(A) for a full and complete reading of its provisions.

139. In any case where such a legal liability is found to exist and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek such reimbursement to the extent of such legal liability. 42 U.S.C. 1396a (a)(25)(B).

**ANSWER:** To the extent paragraph 139 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 139 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. 1396a (a)(25)(B) for a full and complete reading of its provisions.

140. Under the Medicaid rebate provision, any manufacturer that knowingly provides false information “is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information.” “[S]uch civil money penalties are in addition to other penalties as may be prescribed by law.” 42 U.S.C. § 1396r-8(c)(ii) (emphasis added).

**ANSWER:** To the extent paragraph 140 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that 42 U.S.C. § 1396r-8(c)(ii) contains certain provisions regarding penalties for the knowing provision of false information, and respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(ii) for a full and complete reading of its provisions. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140 of the Complaint and therefore denies the same and demands strict proof thereof.

141. New York Social Services Law § 145-b expressly provides for other penalties where false information, such as inaccurate Best Prices, is provided and Medicaid overpays as a

result. Section 145-b expressly provides further that a local social services district has “a right to recover civil damages equal to three times the amount which any figure is falsely overstated. . .”

**ANSWER:** To the extent paragraph 141 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the remaininig allegations in paragraph 141 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

142. In his *Amicus* brief, at 8, the Secretary of HHS wrote:

States obviously have a direct and compelling interest in accurate Best Price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. It is within their [the state’s] statutory authority to investigate and prosecute Medicaid best price violations as alleged in this case.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Complaint and therefore denies the same and demands strict proof thereof.

143. Because the Counties, like the State, are Medicaid payors and receive their share of any Medicaid rebate paid, the Counties also have a direct and compelling interest in accurate Best Price reporting and the rebate program.

**ANSWER:** To the extent paragraph 143 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 143 of the Complaint and therefore denies the same and demands strict proof thereof.

144. At all times relevant hereto, each defendant has intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and

inflated, with the intention and knowledge that the published information would be relied upon by CMS for FUL calculation and by Medicaid, and private payors for calculating drug payments and reimbursements. Defendants' own marketing and sales materials show that defendants market their products based on the spread between reimbursement (based on AWP, FUL, WAC or a WAC equivalent) and actual acquisition cost. Defendants' own marketing documents make clear that they create spread and induce provider purchases based on inflated reimbursement whether their products are single or multi-source. Defendants create spread for their drugs even when they are competing for formulary placement or competing with over-the counter alternatives. Thus, the motivation to improperly inflate reimbursement prices exists whether a drug is brand name, single source, multi-source or generic.

**ANSWER:** Chiron denies the allegations in paragraph 144 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it "intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated." Chiron further denies the characterization of "spread" in paragraph 144. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 144 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

145. Exhibit B hereto lists the drugs that are at issue in this litigation. Every drug listed in Exhibit B was paid for by the County Medicaid Programs based on either AWP or FUL. Exhibit B sets forth, for each drug: (a) the drug's NDC; (b) the drug Name; (c) the reported AWP; (d) the FUL, if one was in place; (e) whether the drug was reimbursed by New York Medicaid based on AWP or FUL; (e) the Actual Acquisition Cost ("AAC") of the drug to entities who are considered Pharmacy Providers by New York Medicaid (i.e., entities that are reimbursed based on AWP or FUL by New York Medicaid); and (f) the spread between the reimbursement amount and the AAC.

**ANSWER:** Chiron admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein and states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Chiron denies the remaining allegations in paragraph 145 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies the characterization of "spread" in paragraph 145.

Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 145 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

146. Exhibit B notes specifically when a defendants' failure to report accurate prices resulted in a false and inflated FUL to be set.

**ANSWER:** Chiron denies the allegations in paragraph 146 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 146 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

147. Exhibit B demonstrates that the prices at which drugs were actually sold to Pharmacy Providers were much lower than the AWP, WACs, or other wholesale prices reported or caused to be reported by defendants and used by Medicaid for reimbursement.

**ANSWER:** Chiron denies the allegations in paragraph 147 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 147 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

148. The spreads on Exhibit B make clear that even a 10 or 12 or 12.75 percent discount off AWP, or reimbursement at the FUL, as New York's Medicaid law provides does not eliminate the damage resulting from defendants' purposeful submission of false and inflated reimbursement price information. The spreads make clear that, by submitting false and inflated data, defendants entirely undermined New York Medicaid's effort to reimburse at EAC.

**ANSWER:** To the extent paragraph 148 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 148 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies the characterization of "spread" in paragraph 148. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in

paragraph 148 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

149. Exhibit B also demonstrates that defendants routinely submitted fraudulent prices for both brand and generic products.

**ANSWER:** Chiron denies the allegations in paragraph 149 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it “routinely submitted fraudulent prices”. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 149 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

150. Each of the generic or multi-source drug manufacturer defendants are aware of the reimbursement prices reported by their competitors, the actual price of their generic competitors’ products, their own sale prices to Medicaid providers, and the FUL. Generic drug manufacturer defendants manipulate their own reported reimbursement prices in order to gain or maintain a competitive advantage in the market for their generic products.

**ANSWER:** Chiron denies the allegations in paragraph 150 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 150 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

151. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000%. A few examples from defendants herein collected by the DOJ in a September 2000 study, are set forth below:

Defendant	Multi-source Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Baxter*	Dextrose**	\$ 928.51	\$ 2.25	41,167%
Baxter*	Sodium Chloride**	\$ 928.51	\$ 1.71	54,199%
Boehringer*	Leucovorin Calcium**	\$ 184.40	\$ 2.76	6,581%
Braun*	Sodium Chloride	\$ 11.33	\$ 1.49	660%
Bristol-Myers Group*	Etoposide (Vepesid) **	\$ 136.49	\$ 34.30	298%
Dey*	Albuterol Sulfate**	\$ 30.25	\$ 9.17	230%
Immunex*	Leucovorin Calcium**	\$ 137.94	\$ 14.58	846%

Defendant	Multi-source Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Pharmacia*	Etoposide	\$ 157.65	\$ 9.47	1,565%
Sicor Group*	Tobramycin Sulfate**	\$ 342.19	\$ 6.98	4,802%
Watson*	Vancomycin HCL	\$ 70.00	\$ 3.84	1,567%

\* Defendants herein

\*\*At issue drugs

**ANSWER:** Chiron denies the allegations in paragraph 151 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies the characterization of “spread” in paragraph 151. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 151 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

152. These reported AWP's are far in excess of the amounts that the manufacturers charged to wholesalers or providers, indeed far higher than any purchase price paid by any participant in the drug distribution chain. In fact, defendants' AWP's are completely fictitious prices that no one ever actually pays. They are created out of thin air based on false pricing data and for the sole purpose of creating a marketable spread as described herein.

**ANSWER:** Chiron denies the allegations in paragraph 152 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies the characterization of “spread” in paragraph 152, and further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 152 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

153. These facts are confirmed by investigations by Congress, the General Accounting Office (“GAO”) and the HHS OIG, and by litigations by the Department of Justice (“DOJ”), various state Attorneys General and U.S. Attorneys, as detailed below.

**ANSWER:** Chiron denies the allegations in paragraph 153 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 153 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

154. The HHS OIG has emphasized that “manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.”

**ANSWER:** Paragraph 154 purports to contain a statement from HHS OIG, but Chiron lacks knowledge or information sufficient to form a belief as to its accuracy because the source thereof is not provided; therefore, Chiron denies the same and demands strict proof thereof. To the extent the source of the statement is provided, the source speaks for itself, and any characterizations thereof are denied.

155. Defendants report wholesale price information that they know does not comply with the HHS OIG’s guidelines, in that they do not account for routine prompt pay discounts, bundled discounts, chargebacks, rebates, free samples, off invoice pricing and other discounts and inducements they routinely offer to wholesalers, chain pharmacies, group purchasing organizations, pharmacists, nursing homes, hospitals, and other distributors who are in a position to increase sales of defendants’ products.

**ANSWER:** Chiron denies the allegations in paragraph 155 of the Complaint as to Chiron and demands strict proof thereof. Chiron further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

156. For example, defendants regularly pay “chargebacks” that are not accounted for in their reported prices. Chargebacks are payments by defendants to drug wholesalers to compensate the wholesaler for its sales of defendants’ drugs to an indirect purchaser to whom the manufacturer has agreed to sell its drugs at a deep discount.

**ANSWER:** Chiron denies the allegations in paragraph 156 of the Complaint as to Chiron and demands strict proof thereof, except states that (i) Chiron contracted for discount pricing for certain products; (2) sold drugs to wholesalers at WAC; and (iii) wholesalers delivered products and Chiron received chargebacks from those wholesalers. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 156 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

157. Defendants also routinely pay prompt pay discounts to wholesalers that are not accounted for in their reported price. Prompt pay discounts are given when the purchaser pays the drug manufacturer within a prescribed period of time. Wholesalers uniformly avail themselves of prompt pay discounts. Other credits, rebates, hidden discounts and financial incentives likewise are routinely provided and not included in the AWP or other wholesale pricing data reported by defendants.

**ANSWER:** Chiron denies the allegation in paragraph 157 of the Complaint as to Chiron and demands strict proof thereof, except states that (i) Chiron's "Wholesaler Price" sometimes referred to as WAC or "ex-factory" price, is the list price at which it makes its products available for sale directly to wholesalers; (ii) payment terms provide for a customary 2% bona fide service fee credit for prompt payment; (iii) when Chiron takes a price increase on a product, Chiron has, for inventory management purposes, permitted at times certain wholesalers to purchase a certain quantity of the product at the old price for a limited time; and (iv) because WAC is the list price, it does not reflect such discounts and allowances. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 157 of the Complaint as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

158. By increasing the spread on its drugs, each defendant seeks to influence drug-selecting entities such as physicians, pharmacies, Nursing homes, long-term care facilities, PBMs and/or others in the drug distribution chain to increase their purchases of its drugs.

Defendants engage in this purposeful manipulation for the sole and express purpose of creating the spread to create demand for their products. Manufacturers market the spread to PBMs to gain inclusion into a PBM's formulary, and to wholesalers and pharmacists to be the exclusive supplier of a multi-source drug or to otherwise incentivize them to distribute defendants' products. PBMs and pharmacists benefit by pocketing the difference between the reported AWP and the actual cost they pay for the drug.

**ANSWER:** Chiron denies the allegations in paragraph 158 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 158 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

159. PBMs specialize in the administration and management of prescription benefit programs. Their clients include HMOs, employers, preferred provider organizations and other health insurers. Three PBMs, AdvancePCS/Caremark, Express Scripts and Medco Health, together control eighty percent of the PBM market and supply the prescription drugs of approximately 210 million people in the United States.

**ANSWER:** Chiron admits that PBMs are involved in administering and managing prescription drug benefit programs. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 159 of the Complaint and therefore denies the same and demands strict proof thereof.

160. PBMs operate in two primary businesses: First, PBMs contract with pharmaceutical manufacturers, retail pharmacies, and health plans to decide which drugs should be included in formularies, to bill health plans for prescription drug payments on behalf of plan participants, and to pay the pharmacies. Second, PBMs operate their own proprietary mail order pharmacies.

**ANSWER:** Chiron admits that certain PBMs operate mail order pharmacies. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 160 of the Complaint and therefore denies the same and demands strict proof thereof.

161. PBMs' historic business model was to procure drugs for their health plan client in exchange for administrative fees. According to the Wall Street Journal, "[t]raditionally, PBMs received only modest administrative fees for arranging prescriptions at cost." Barbara Martinez,

*Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making \$170 on just 90 Pills,* WSJ, March 31, 2003, at A1.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 161 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 161 refer to articles or reports, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to *Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making \$170 on just 90 Pills,* WSJ, March 31, 2003, at A1 for a full and complete reading of its contents.

162. This model has changed in recent years such that PBMs now are “increasingly . . . reducing those fees and trying to take advantage of the “spread” between pharmacy prices and what corporate and government clients pay. Express Scripts say most of its contracts now include spread pricing.” *Id.*

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 162 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 162 refer to articles or reports, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to *Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making \$170 on just 90 Pills,* WSJ, March 31, 2003, at A1 for a full and complete reading of its contents.

163. The following is an example of a typical PBM transaction and a description of the contracts that underpin it. A health plan participant is prescribed a drug by a physician. The participant fills the prescription at a PBM-approved pharmacist, paying only the co-pay. The pharmacist buys the drug either directly from the manufacturer or from a wholesaler. The pharmacist then bills the PBM for the drugs it sells to the patient. The PBM has a contract with

the retail pharmacy to pay a price at a certain discount off AWP, *e.g.*, AWP minus 15%. The PBM in turn bills the health plan for this drug. However, the PBM has a separate contract with the health plan, entitling it to payment at a different, higher rate, *e.g.*, AWP minus 10%. Thus, in addition to any administrative fee the PBM receives, the PBM receives the spread between the contractual payment it receives from the health plan and the contractual payment it makes to the pharmacist. Furthermore, if the PBM operates its own mail-order pharmacy that health plan members are required to use, the PBM reaps the pharmacist's share of the spread as well.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 163 of the Complaint and therefore denies the same and demands strict proof thereof.

164. In the Introduction to this Complaint, plaintiffs set forth an example of how PBMs and pharmacists profit from the spread in the case of Fluoxetine.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 164 of the Complaint and therefore denies the same and demands strict proof thereof.

165. PBMs select their formularies based on the profits they can make, including the spread between actual price and AWP, and taking into account rebates, discounts, chargebacks and other incentives that the manufacturers provide:

PBMs develop relationships with manufacturers that provide lower pricing (through rebates) when a particular drug is on the formulary.... In general, the level of rebates increases if the PBM increases a greater market share for a drug within a defined class of prescriptions with similar therapeutic effects.

*Providing Prescription Drug Coverage Through Medicare: The Role of Pharmacy Benefit Managers*, U.S. Senate Committee on Finance (Mar. 29, 2000), at 4-5 found at <http://www.senate.gov/~finance/3-29mcca.htm>.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 165 of the Complaint and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to *Providing Prescription Drug Coverage Through Medicare: The Role of Pharmacy Benefit Managers*, U.S. Senate

Committee on Finance (Mar. 29, 2000), at 4-5, found at <http://www.senate.gov/~finance/3-29mcca.htm>, for a full and complete reading of its contents.

166. Defendants know and understand that third-party payors and PBMs rely on the First Data Bank (“FDB”) and other publishers to determine the reimbursement [sic] prices of the covered drugs, both brand name and generic. Because defendants control the published reimbursement prices, defendants know and understand that they can manipulate the providers’ and PBMs’ profits, gained at the expense of third-party payors, including the Counties, to incentivize these providers and PBMs to prescribe their drugs and/or to include their drugs in a drug formulary by inflating the reimbursement prices.

**ANSWER:** Chiron denies the allegations in paragraph 166 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it “control[s] the published reimbursement prices.” Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 166 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

167. Because the PBMs consider their contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. Nor are they informed of the actual prices that pharmacies pay for the drugs.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 167 of the Complaint and therefore denies the same and demands strict proof thereof.

168. At all times relevant hereto, each defendant executed a Rebate Agreement in which it promised to comply with its contractual terms and with the requirements of the Medicaid rebate provision, 42 U.S.C. § 1396-r-8.

**ANSWER:** To the extent paragraph 168 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that it has executed a rebate agreement with HHS, and states that the rebate agreement speaks for itself and any characterizations thereof are denied. Chiron denies the remaining allegations in paragraph 168 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 168 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 168 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396-r-8 for a full and complete reading of its provisions.

169. At all times relevant hereto, each defendant knew that the purpose of the rebate agreements it executed was to pass on Medicaid pharmacy cost savings to the State of New York and its local social service districts, including the Counties.

**ANSWER:** To the extent paragraph 169 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that it pays rebates to the State of New York and that such rebates lower the State of New York's cost of prescription drugs for Medicaid patients. Chiron denies the remaining allegations in paragraph 169 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 169 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

170. At all relevant times hereto, each defendant knowingly calculated its Best Prices excluding factors that it was statutorily and/or contractually required to include, resulting in the payment of rebates that were less than required.

**ANSWER:** To the extent paragraph 170 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 170 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 170 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

171. The same routine discounts, rebates, free samples and other inducements offered to providers but excluded in setting AWP are also excluded from defendants' calculations of Best Price. These include chargebacks, prompt pay discounts, free samples distributed by sales representatives, and other credits, up front and back end rebates off invoice transactions, and hidden discounts and financial incentives.

**ANSWER:** To the extent paragraph 171 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 171 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 171 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

172. In addition, defendants routinely bundle deeply discounted or free drugs with other drugs. The Model Rebate Agreement executed by every defendant herein expressly provides that for bundled sales the discount must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Defendants do not properly allocate bundled discounts when calculating Best Price.

**ANSWER:** To the extent paragraph 172 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron admits that it has executed a rebate agreement with HHS, and states that the rebate agreement speaks for itself and any characterizations thereof are denied. Chiron denies the remaining allegations in paragraph 172 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

173. Certain defendants also engage in re-labeling schemes to avoid reporting Best Price. Federal law expressly prohibits this practice. 42 U.S.C. § 1396r-8(c)(ii). For example, in

2003, two defendants herein, Bayer and GSK, agreed to pay \$344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their Best Price for certain drugs. In their wrongful scheme, known as “lick and stick,” they sold drugs to Kaiser Permanente Medical Care Program (the nation’s largest HMO) at deep discounts, but avoided including these discounts in their Best Price calculations by re-labeling the products with new NDC codes before sale.

**ANSWER:** To the extent paragraph 173 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 173 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 173 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(ii) for a full and complete reading of its provisions.

174. As described below, the HHS OIG has documented that such repackaging schemes are widespread. OIG, Medicaid Drug Rebates – Sales To Repackagers Excluded From Best Price Determinations, at 1, 4 (March 2001).

**ANSWER:** Chiron denies the allegations in paragraph 174 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraphs 174 refer to statutes, regulations, or reports, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to OIG, Medicaid Drug Rebates – Sales To Repackagers Excluded From Best Price Determinations, at 1, 4 (March 2001) for a full and complete reading of its contents.

175. On information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs. These inducements, including educational grants, volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug might really only cost the purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a “grant,” “rebate” or “credit memo” in the amount of \$50, the transaction would truly cost just \$5 per unit net. Through all these off-invoice means, drug purchasers are provided the substantial discounts that induce their patronage while maintaining the fiction of a higher invoice price – the price that corresponds to reported AWP and inflated reimbursement from Medicaid.

**ANSWER:** Chiron denies the allegations in paragraph 175 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 175 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

176. As detailed below, a number of defendants herein, including Merck, Tap and Eli Lilly, also are under investigation for abusing the nominal price exception to Best Price reporting, created by Congress as a public policy exception to encourage drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good, without the manufacturer having to pay increased rebates because of those sales. The exception allows drug companies to exclude from their Best Price calculations drugs with prices less than 10% of AMP. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III).

**ANSWER:** To the extent paragraph 176 of the Complaint states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 176 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III) for a full and complete reading of its provisions.

#### **ANSWER TO GOVERNMENT INVESTIGATIONS**

177. DOJ, GAO, HHS OIG, and a number of Congressional and Senate committees have investigated and are continuing to investigate defendants for questionable practices

regarding the reporting of wholesale pricing information, Best Price, and other non-compliance with Medicaid rebate provision.

**ANSWER:** Chiron admits that on October 6, 1997, and July 27, 2000, respectively, the Department of Health and Human Services Office of Inspector General issued a subpoena *duces tecum* to Chiron seeking documents and pricing information from it, and states that the federal government has taken no action adverse to Chiron in relation to such subpoenas. Chiron denies the remaining allegations in paragraph 177 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

178. The House Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. On June 26, 2003, Chairman Billy Tauzin (R-La.) and Oversight and Investigations Subcommittee Chairman James Greenwood (R-PA) wrote as follows to 26 drug companies, including many defendants herein:<sup>10</sup>

The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursement rates under the Medicare program. In that investigation, the Committee uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for \$7.50, when the reported price for Medicare was \$740. The taxpayer therefore reimbursed the doctor almost \$600 for dispensing the drug and the cancer patient

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<sup>10</sup> The targeted companies include defendants Abbott Labs; Alpharma; Aventis Pharmaceuticals; Barr Labs; Bristol Myers; Dey; Ethex; Eli Lilly; Geneva; GlaxoSmithKline; IVAX; Johnson & Johnson; Mylan Pharmaceuticals; Par Pharmaceuticals; Pfizer, Purepac; Roche; Roxane; Schering-Plough; TEVA; UDL Labs; Warrick Pharmaceuticals; and Watson.

had a \$148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.

The Committee has similar concerns regarding drug prices in Medicaid, which has a substantially larger pharmaceutical benefit than Medicare.

House Committee on Energy and Commerce, June 26, 2003 Press Release, "Tauzin, Greenwood Expand Medicaid Fraud Investigation."

**ANSWER:** Chiron was not one of the twenty-six (26) drug companies referenced in paragraph 178 or its footnote's allegations and averments, thus no response is required. To the extent a response is deemed required, Chiron states that it is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178 and its footnote and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to the House Committee on Energy and Commerce Press Release dated June 26, 2003 referenced in paragraph 178 of the Complaint for a full and complete reading of its content, but denies any characterization thereof.

179. The letter requests extensive and specific detail about the subject companies' sales, AWP's, AMP's, and their records relating to calculation of Best Prices and their use of the nominal price exception.

**ANSWER:** Chiron was not one of the twenty-six (26) drug companies referenced in paragraph 179 or its footnote's allegations and averments, thus no response is required. To the extent a response is deemed required, Chiron states that it is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179 and its footnote and therefore denies the same and demands strict proof thereof.

180. This investigation is continuing. At a hearing on December 7, 2004, Chairman Joe Barton noted the huge inflation of the prices paid by Medicaid, particularly for generic drugs. *House Hearing*, Tr. at 3-4,5. Defendant Dey's chief financial officer testified as follows:

Why doesn't Dey lower its AWP on generic drugs? The simple answer is that given the system that now exists our customers won't buy from us if we lower our AWP.

*Id.* at 117-118 (testimony of Pamela Marrs, Senior Vice President & CFO, Dey, Inc.). Similarly, the Senior Product Manager for defendant Roxane Laboratories testified that no one would buy their product if the AWP was too low. *Id.* at 134 (testimony of Leslie Paoletti, Roxane Laboratories, Inc.). Many of the drugs under Congressional scrutiny, including Albuterol, Bupirone, Fluoxetine, Buspar, Celebrex, and Zyprexa, are drugs at issue here and for which the Counties' Medicaid Programs spend large sums. *See* Exhibit A.

**ANSWER:** Chiron refers to the Hearing Transcript referenced in paragraph 180 of the Complaint for its content, but denies any characterization thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 180 and therefore denies the same and demands strict proof thereof.

181. On April 29, 2004, the Senate Finance Committee sent letters to 19 drug companies<sup>11</sup> focusing on whether those companies exploited the nominal price exception. The Committee wrote:

We understand that some drug manufacturers may be using the Nominal Price Exception as part of their commercial pricing practices. These practices could undermine the purposes of the Medicaid Best Price policy and may be costing taxpayers hundreds of millions of dollars through reduced Medicaid rebates.

Senate Finance Committee Press Release, April 29, 2004, *Grassley, Baucus Ask Drug Manufacturers Question About How They Price Drugs For Medicaid*.

**ANSWER:** Chiron was not one of the nineteen (19) drug companies referenced in paragraph 181 or its footnote's allegations and averments, thus no response is required. To the extent a response is deemed required, Chiron states that it is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181 and its

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<sup>11</sup> Target companies include defendants GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Pfizer, Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals, Inc., Abbott Laboratories, Hoffman-La Roche Inc., TAP Pharmaceutical Products Inc., Schering-Plough Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., and Sanofi-Synthelabo.

footnote and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to the April 29, 2004 Senate Finance Committee Press Release, *Grassley, Baucus Ask Drug Manufacturers Question About How They Price Drugs For Medicaid*, referenced in paragraph 181 of the Complaint for a full and complete reading of its content, but denies any characterization thereof.

182. The House and Senate Medicaid investigations described above follow comparable investigations regarding Medicare in 2000 – 2001. Congressman Pete Stark (D-Ca.) chaired that investigation.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182 and therefore denies the same and demands strict proof thereof.

183. In a letter dated September 28, 2000, Congressman Stark wrote to the president of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), of which most of the Defendants are members, as follows:

Drug company deception costs federal and state governments, private insurers and others billions of dollars per year in excessive drug costs. This corruptive scheme is perverting the financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare’s current limited drug benefit. Furthermore, these deceptive, unlawful practices have a devastating financial impact upon the states’ Medicare Program. . . .

The evidence I have obtained indicates that at least some of your members have knowingly and deliberately falsely inflated their representations of the average wholesale price (“AWP”), wholesaler acquisition cost (“WAC”) and direct price (“DP”) which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The evidence clearly establishes and exposes the drug manufacturers themselves that were the direct and sometimes indirect sources of the fraudulent misrepresentation of prices. Moreover, this unscrupulous “cartel” of companies has gone to extreme lengths to “mask” their drugs’ true prices and their fraudulent conduct from federal and state authorities. I have learned that the difference between the falsely inflated representations of AWP and WAC

versus the true prices providers are paying is regularly referred to in your industry as “the spread.” . . .

The evidence is overwhelming that this “spread” did not occur accidentally but is the product of conscious and fully informed business decisions by certain PhRMA members. . . .

September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Cong. Rec., Extension of Remarks at E1622.

**ANSWER:** Chiron refers to the September 28, 2000 letter authored by Congressman Peter Stark and referenced in paragraph 183 of the Complaint for its content, but denies Plaintiffs’ characterization thereof and respectfully refers the Court to 146 Cong. Rec. E1622 (daily ed., September 28, 2000) (September 28, 2000, letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C.) for a full and complete reading of its contents. Chiron denies the allegations in paragraph 183 of the Complaint as to Chiron and demands strict proof thereof. Chiron further states that it has never been a member of PhRMA. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 183 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

184. Congressman Stark came to the following five “shocking conclusions”:

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to

arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

*Id.* at E1623-24.

**ANSWER:** Chiron refers to the September 28, 2000 letter authored by Congressman Peter Stark and referenced in paragraph 184 of the Complaint for its content, but denies Plaintiffs' characterization thereof and respectfully refers the Court to 146 Cong. Rec. E1622 (daily ed., September 28, 2000) (September 28, 2000, letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C.) for a full and complete reading of its contents. Chiron denies the allegations in paragraph 184 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 184 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

185. The investigation led by Congressman Stark concluded that defendants employed a number of financial inducements to stimulate the sales of their drugs at the expense of both Medicare and Medicaid. Such inducements include the practices described herein, i.e., volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while keeping high the cost of the drug to government programs:

Some drug companies have also utilized a large array of other impermissible inducements to stimulate sales of their drugs. These inducements, including bogus "educational grants", volume discounts, rebates or free goods, were designed to result in a lower

net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser half that amount. Given, for instance, a subsequent shipment of an additional ten units at no charge, or a “grant”, “rebate” or “credit memo” in the amount of \$50, the transaction would truly cost a net of only \$5.00 per unit. Through all these “off-invoice” means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price-the price that corresponded to reported AWP’s and inflated reimbursement . . .

Cong. Rec., Sept. 28, 2000, at E1623.

**ANSWER:** Chiron refers to the September 28, 2000 letter authored by Congressman Peter Stark and referenced in paragraph 183 of the Complaint for its content, but denies Plaintiffs’ characterization thereof and respectfully refers the Court to 146 Cong. Rec. E1622 (daily ed., September 28, 2000) (September 28, 2000, letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C.) for a full and complete reading of its contents. Chiron denies the allegations in paragraph 185 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it “employed a number of financial inducements to stimulate the sales of [its] drugs at the expense of both Medicare and Medicaid.” Answering further, Chiron states that it is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 185 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

186. A September 21, 2000 GAO Report determined that actual retail prices for top Medicaid/Medicare drugs, such as Albuterol and Ipratropium bromide, were 85 percent and 75 percent less than their AWP’s. Applying this range of percentages to New York City’s Medicaid costs, the overcharges add up to millions of dollars annually. GAO, *Payments for Covered Outpatient Drugs Exceed Providers’ Cost*, Sept. 2001 (GAO-01-1118) at 4.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 186 and therefore denies the same and demands strict

proof thereof. Chiron respectfully refers the Court to GAO, *Payments for Covered Outpatient Drugs Exceed Providers' Cost*, Sept. 2001 (GAO-01-1118) at 4, for a full and complete reading of its contents.

187. That same GAO report found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP.

GAO-01-1118 at 11-12.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 187 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to GAO, *Payments for Covered Outpatient Drugs Exceed Providers' Cost*, Sept. 2001 (GAO-01-1118) at 4, for a full and complete reading of its contents.

188. In 2002, the OIG issued a series of reports on pharmacy overcharges to the Medicaid program, based on data collected in 1994 and again in 1999. In its September 2002 report, the OIG summarized its findings. Pharmacies' actual acquisition cost for brand name prescription drugs was on average 21.8% below AWP. For generic drugs, actual acquisition costs were 65.9% below AWP. These numbers reflected considerably increased spreads as compared to the earlier data, which showed spreads of 18.3% and 42.5% for brand name and generic drugs respectively. HHS OIG, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Costs of Prescription Drugs* (A-06-02-00041) (September 16, 2002), at 1.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 188 and therefore denies the same and demands strict proof thereof, except Chiron specifically denies the characterization of “spread” in paragraph 188. Chiron respectfully refers the Court to HHS OIG, *Medicaid Pharmacy – Additional*

*Analyses of the Actual Acquisition Costs of Prescription Drugs* (A-06-02-00041) (September 16, 2002), at 1, for a full and complete reading of its contents.

189. In 2003, the OIG warned that drug pricing practices in the private sector may have significant effects on Medicaid rebates:

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, *manufacturers have a strong financial incentive to hide de facto pricing concessions to other purchasers to avoid passing on the same discounts to the states*. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731-35 (May 5, 2003) (emphasis supplied).

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 189 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731-35 (May 5, 2003), for a full and complete reading of its contents.

190. A March 27, 2001 report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG studied the rebate issues for the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year (FY) 1999. It found that many manufacturers failed to include in their Best Price calculations submitted to the federal government discounted sales to repackagers, which buy drugs in bulk and then repackage them in smaller quantities for distribution:

7 out of 53 manufacturers excluded sales to 8 repackagers, 3 of which were HMO repackagers. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling

\$80.7 million for FY 1999 were lost because sales to HMOs were excluded from the best price determinations.

*Id.* at 1. The report found that “[i]n some instances the sales to the HMOs were at prices as much as 75 percent below the reported best price.” *Id.* at 4. Given the Model Rebate Agreement definition of Best Price, quoted above, these sales to repackagers should be accounted for in Best Price calculations. Yet they routinely are not.

**ANSWER:** Chiron denies the allegations in paragraph 190 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to the March 27, 2001, report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG, at 1, 4, for a full and complete reading of its contents.

191. The report went on to say that this review was a follow up to previous investigations conducted in response to congressional inquiries. Based on a more limited number of drugs and repackagers it was found that that two “repackagers were HMOs and that they were purchasing drugs significantly below the manufacturers’ reported best prices.” This limited study found a loss of \$27.8 million in Medicaid rebates for FY 1998. *Id.* at 1.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to the March 27, 2001, report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG, at 1, 4, for a full and complete reading of its contents.

192. The report “recommended that the Health Care Financing Administration (HCFA) [now CMS] require drug manufacturers who excluded sales to HMOs from their Best Price to repay the lost rebates.” *Id.* at cover page. Rep. Henry A. Waxman (D-CA), who requested the report, said “This report shows that drug manufacturers have used drug repackaging to evade paying rebates to Medicaid.” *Drug Companies’ Repackaging Scheme Costs Taxpayers Over \$100 Million In 1998 And 1999*, April 5, 2001, pg. 1 of 1, available at [http://www.house.gov/reform/min/pdfs/pdf\\_inves/pdf\\_medi\\_drug\\_IG\\_press.pdf](http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_medi_drug_IG_press.pdf).

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to the March 27, 2001, report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG, at 1, 4, for a full and complete reading of its contents.

193. The GAO, HHS OIG, and DOJ investigations of the fraudulent pricing practices undergirding this complaint are further described in the defendant-specific allegations below.

**ANSWER:** Chiron denies the allegations in paragraph 193 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 193 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO ALLEGATIONS PARTICULAR TO THE  
COUNTIES AND THE INDIVIDUAL DEFENDANTS**

194. The following examples are merely illustrative of each defendant's unlawful activity, and are not intended to be an exact or exhaustive recitation of all of such activity engaged in by each defendant. Instead, these allegations describe the wrongful conduct of each defendant in sufficient detail and particularity to support the liability allegations to each. The particular pharmaceutical products identified below are similarly not intended to be an exhaustive list as to all products or NDCs for which each defendant engaged in misconduct. Additional detail is peculiarly within defendant's control pending discovery.

**ANSWER:** To the extent the allegations of paragraph 194 of the Complaint state legal conclusions and/or arguments and/or characterizations, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 194 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

195. At all times relevant hereto, each of the following defendants entered into contracts with GPOs, hospitals, PBMs and other purchasers whereby such purchasers were

guaranteed a price for defendants' drugs that was deeply discounted off the WACs, Direct Prices, AWP's and/or other reimbursement price information defendants supplied to publishers for reimbursement price reporting purposes. At times these reduced prices were in the form of up front discounts. At times, the reduced prices were in the form of guaranteed rebates. The WACs, Direct Prices, AWP's and/or other reimbursement price information defendants supplied to publishers did not take into account these deeply discounted prices (referred to herein as "available prices") Thus, the WACs, Direct Prices, AWP's and/or other reimbursement price information provided by defendants were false and inflated. The purpose of the inflation was to create the marketable spread referred to herein, which defendants used to increase demand for their products at the expense of those who reimbursed for drugs based on AWP and FUL, such as the County Medicaid Programs.

**ANSWER:** Chiron denies the allegations in paragraph 195 of the Complaint as to Chiron and demands strict proof thereof, except Chiron admits that its contracts with purchasers sometimes included discounts. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

196. Exhibit A hereto presents a defendant-by-defendant summary of (a) the total expenditures at issue for that defendant; (b) the number of NDCs at issue for that defendant; (c) the number of NDCs at issue because of alleged AWP fraud; and (d) the number of NDCs at issue because of alleged FUL fraud.

**ANSWER:** Chiron denies the allegations in paragraph 196 of the Complaint and Exhibit A attached thereto as to Chiron and demands strict proof thereof. Chiron specifically denies the accuracy of the data listed in Exhibit A and states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**Paragraphs 197-385 (Allegations concerning various other Defendants)**

**ANSWER:** The allegations in paragraphs 197-385 are directed to other defendants and require no response from Chiron. To the extent a response is deemed required, Chiron is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 197-385 and therefore denies the same and demands strict proof thereof.

#### **L. CHIRON**

386. As summarized in Exhibit A, the County Medicaid Programs spent over \$14 million for the 8 at-issue Chiron NDCs between 1992 - 2005 alone.<sup>25</sup> The specific Chiron NDCs for which the Counties seek relief are set forth in Exhibit B-12 hereto.

**ANSWER:** Chiron denies the allegations in paragraph 386 and numbered footnote 25 of the Complaint and the exhibits referenced therein and demands strict proof thereof. Chiron specifically denies the accuracy of the data listed in Exhibit A and Exhibit B and states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Additionally, Chiron states that the specific Chiron NDCs alleged by Plaintiffs to be at issue are found in Exhibit B-11, not B-12.

387. At all times relevant hereto, Chiron has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-12, Chiron has created such spreads.

**ANSWER:** Chiron denies the allegations in paragraph 387 of the Complaint and Exhibit B-12 referenced therein and demands strict proof thereof. Chiron specifically denies the accuracy of the data listed in Exhibit B and states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Additionally, Chiron states that the specific Chiron NDCs alleged by Plaintiffs to be at issue are found in Exhibit B-11, not B-12.

388. Chiron has instructed its sales force to market the spread for its products. Chiron has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of

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<sup>25</sup> The claims of the County Medicaid Programs are not confined to this time period.

spread. These worksheets also described the AWP of the Chiron competitors to demonstrate the advantage of purchasing Chiron products with their inflated AWP.

**ANSWER:** Chiron admits that it was aware of the list prices and AWP of some drugs made by other manufacturers. Chiron denies the remaining allegations in paragraph 388 of the Complaint and demands strict proof thereof.

389. As set forth in the table below, Chiron aggressively sold its products at prices that were significantly lower than the spread.

Defendant Chiron's Prices & Spreads From 1995 Contract					
Drug	NDC	Contract Price	AWP	Provider's Gross Profit or Spread	Spread as a % of Contract Price
Cytarabine, Lyoph	53905131-10	\$2.88/vial	\$62.50	\$59.62	2070%
Cytarabine, Lyoph	53905132-10	\$8.75/vial	\$250.00	\$241.25	2757%
Cytarabine, Lyoph	53905133-01	\$21.50/vial	\$508.00	\$486.50	2263%
Cytarabine, Lyoph	53905134-01	\$43.00/vial	\$98.90	\$55.90	130%
Doxorubicin Solution	53905235-10	\$13.92/vial	\$47.37	\$33.45	240%
Doxorubicin Solution	53905236-10	\$27.26/vial	\$94.70	\$67.44	247%
Doxorubicin Solution	53905237-01	\$68.15/vial	\$236.74	\$168.59	247%
Doxorubicin Solution	53905238-01	\$283.50/vial	\$945.98	\$662.48	234%
Leuvocorin, Solution	53905051-01	\$2.30/vial	\$184.38	\$182.08	7917%
Leuvocorin, Solution	53905052-01	\$3.75/vial	\$350.00	\$346.25	9233%
Leuvocorin, Solution	53905053-01	\$9.51/vial	\$78.00	\$68.49	720%
Methotrexate, PFS	53905031-10	\$2.30/vial	\$6.88	\$4.58	199%
Methotrexate, PFS	53905032-10	\$3.22/vial	\$8.75	\$5.53	172%
Methotrexate, PFS	53905033-10	\$4.35/vial	\$17.50	\$13.15	302%

Defendant Chiron's Prices & Spreads From 1995 Contract					
Drug	NDC	Contract Price	AWP	Provider's Gross Profit or Spread	Spread as a % of Contract Price
Methotrexate, PFS	53905034-10	\$4.60/vial	\$26.88	\$22.28	484%

**ANSWER:** Chiron denies the allegations in paragraph 389 of the Complaint and demands strict proof thereof. Chiron specifically denies the accuracy of the data and information contained in the table created by Plaintiffs, above, and states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Additionally, Chiron states that the data contained in the table created by Plaintiffs, above, purports to contain data from 1995 and thus is beyond the applicable timeframe at issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005). Chiron further states that it sold its interests in these products to another pharmaceutical manufacturer in 1996 before the applicable timeframe at issue in the litigation. *See id.*

390. In 1995, Chiron aggressively marketed the spread for subject drugs Leucovorin Injection 200 mg (NDC 53905-0053-01) and for Doxorubicin HCL, sol, 200 mg MDV (NDC 53905-0238-01). In an advertisement in 1995, Chiron offered both of these drugs at prices significantly discounted to AWP. Chiron caused per vial AWP's of \$78.00 and \$945.98 to be reported for Leucovorin 200 mg and Doxorubicin, respectively, and highlighted this fact in their advertisement. The advertisement also highlighted acquisition costs of \$9.67 for 200 mg Leucovorin and \$259.00 for 200 mg Doxorubicin. These acquisition costs and AWP's result in spreads of 706% for Chiron's 200 mg Leucovorin, and 265% for Chiron's 200 mg Doxorubicin.

**ANSWER:** Chiron denies the allegations in paragraph 390 of the Complaint and demands strict proof thereof. Chiron states that pursuant to the Court's July 30, 2008 ruling on Chiron's individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Additionally, Chiron states that the allegations contained in paragraph 390 purport to contain data from 1995 and thus is beyond the applicable timeframe at

issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005). Chiron further states that it sold its interests in the products contained in paragraph 390 to another pharmaceutical manufacturer in 1996 before the applicable timeframe at issue in the litigation. *See id.*

391. This advertisement granted customers 2 free vials of Leucovorin 200 mg for every 10 ordered, and 1 free vial of Doxorubicin for every 10 ordered. In addition to this example, Chiron has utilized other impermissible off-invoice inducements to stimulate sales of its drugs without accounting for them in its WAC, AWP, or Best Prices. These inducements were designed to result in a lower net cost to the provider while concealing actual wholesale price beneath a high invoice price. By utilizing “off-invoice” inducements, Chiron provided purchasers with substantial discounts meant to gain their patronage while maintaing [sic] the fiction of a higher wholesale price.

**ANSWER:** To the extent paragraph 391 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 391 of the Complaint and demands strict proof thereof. Additionally, Chiron states that the allegations contained in paragraph 391 purport to contain data and information from 1995 and thus is beyond the applicable timeframe at issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005). Chiron further states that it sold its interests in the products contained in paragraph 391 to another pharmaceutical manufacturer in 1996 before the applicable timeframe at issue in the litigation. *See id.*

392. Chiron has routinely sold subject drugs Acetylcystine (NDC 53905-0211-03, 53905-0212-03), Doxorubicin (NDC 53905-0213-03, 53905-0214-03), Cytarbine (53905-0131-10, 53905-0131-20), and Doxorubicin HCL (NDC 53905-0231-10, 53905-0232-06) among others at spreads that ranged between 100 and 400 percent.

**ANSWER:** Chiron denies the allegations in paragraph 392 of the Complaint and demands strict proof thereof. Chiron states that pursuant to the Court’s July 30, 2008 ruling on Chiron’s individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC

63430006501) remain at issue. Additionally, Chiron states it sold its interests in the products contained in paragraph 392 to another pharmaceutical manufacturer before the applicable timeframe at issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005).

393. Between 1995 and 1998, Chiron kept its AWP for Mitomycin 20 mg, NDCs 53905-0252-01 and 55390-0252-01 at \$434.60, while its wholesale price decreased each year.

<b>PERCENTAGE OF “SPREAD “BETWEEN CHIRON’S REPORTED AWP AND THE TRUE COST FOR MITOMYCIN 20 MG, NDC #s 53905-0252-01 AND 55390-0252-01</b>			
<u><b>Year</b></u>	<u><b>AWP</b></u>	<u><b>TRUE COST</b></u>	<u><b>Percent “Spread”</b></u>
1995	\$434.60	\$338.00	28%
1996	\$434.60	\$260.00	67%
1997	\$434.60	\$190.00	129%
1998	\$434.60	\$152.95	184%

**ANSWER:** Chiron denies the allegations in paragraph 393 of the Complaint and demands strict proof thereof. Chiron states that pursuant to the Court’s July 30, 2008 ruling on Chiron’s individual Motion to Dismiss, only Proleukin (NDC 53905099101) and TOBI® (NDC 63430006501) remain at issue. Additionally, Chiron states that the allegations contained in paragraph 393 purport to contain data and information from 1995-1996 and thus is beyond the applicable timeframe at issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005). Chiron further states that it sold its interest in the product contained in paragraph 393 to another pharmaceutical manufacturer in 1996 before the applicable timeframe at issue in the litigation. *See id.*

394. If the AWP stayed the same, but the price decreased as set forth below, the reported AWP cannot be an “average” wholesale price.

**ANSWER:** Chiron states that paragraph 394 appears to be incomplete, as Plaintiffs allege “but the price decreased as set forth below” but fail to actually set forth anything “below” paragraph 394 that is relevant and/or responsive to paragraph 394. Therefore, Chiron states that

it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 394 of the Complaint and therefore denies the same and demands strict proof thereof.

395. Chiron is the target of multiple government investigations. Chiron has received document subpoenas from the Office of the Inspector General of the United States Department of Health and Human Services. The OIG is investigating pharmaceutical industry practices concerning reporting of average wholesale price for products covered by Medicare and Medicaid. Chiron stated that “the Office of the Inspector General’s investigation is connected to a pending, but as yet unserved, qui tam (whistle blower) lawsuit, in which Chiron and other companies are named defendants.” Chiron 10-K (For fiscal year ended December 31, 2003) at 20 (Mar. 3, 2004).

**ANSWER:** Chiron admits that on October 6, 1997, and July 27, 2000, respectively, the Department of Health and Human Services Office of Inspector General issued a subpoena *duces tecum* to Chiron seeking documents and pricing information from it, and states that the federal government has taken no action adverse to Chiron in relation to such subpoenas. Chiron denies Plaintiffs accurately quote a select portion its 2003 10-K and states that the accurate statement from its 2003 10-K is: “*It appears that* the Office of the Inspector General’s investigation is connected to a pending, but as yet unserved, qui tam (whistle blower) lawsuit, in which Chiron and other companies are named defendants.” (emphasis added) Chiron respectfully refers the Court to its 2003 10-K Annual Report for fiscal year ending December 31, 2003, which Chiron filed on or about March 3, 2004, for a full and complete reading of its contents. It is available at <http://www.secinfo.com/dVut2.1684.htm>. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 395 and therefore denies the same and demands strict proof thereof.

396. Additionally, the Attorneys General of Florida and Kentucky informed Chiron in 2003 that they were investigating Chiron’s calculation and reporting of the AMP and Best Price to the Center for Medicare and Medicaid Services and the Health Care Financing Administration. *Id.* On information and belief those investigations are ongoing.

**ANSWER:** Chiron denies the allegations in paragraph 396 of the Complaint and demands strict proof thereof. Chiron further states that it has not been sued by either Florida or Kentucky in connection with pharmaceutical pricing. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegation in paragraph 396 that “[o]n information and belief those investigations are ongoing[,]” and therefore denies the same and demands strict proof thereof.

397. In September 2000, the Office of the Attorney General of the State of California Department of Justice subpoenaed Chiron, focusing on pricing of certain generic oncology drugs sold by Cetus-Ben Venue under the Medi-Cal program. On information and belief, that investigation is ongoing.

**ANSWER:** Chiron admits that on September 29, 2000, the Attorney General of the State of California served a subpoena *duces tecum* on Cetus Oncology seeking *inter alia* documents and pricing information for certain generic drugs Cytarabine, Doxorubicin HCL, Etoposide, Leucovorin Calcium, and Methotrexate, and states that the State of California took no action adverse to Chiron in relation to such subpoena. Additionally, Chiron states that it sold these products before the applicable timeframe at issue in the litigation. *See* CMO No. 33, ¶ 7 (limiting the time period for discovery to the period 1997-2005). Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegation in paragraph 397 that “[o]n information and belief, that investigation is ongoing[,]” and therefore denies the same and demands strict proof thereof.

398. Chiron’s 2003 10-K reports:

“The Office of the Inspector General of the United States Department of Health and Human Services is investigating pharmaceutical industry practices concerning reporting of average wholesale prices for products covered by Medicare and Medicaid. Chiron and a number of other companies have received document subpoenas in connection with that investigation. Chiron has produced documents responsive to two subpoenas, which relate

specifically to pricing of certain generic oncology drugs sold by Cetus-Ben Venue Therapeutics, a joint venture between Chiron and Ben Venue Laboratories. Chiron sold its interest in that joint venture in 1996. It appears that the Office of the Inspector General's investigation is connected to a pending, but as yet unserved, qui tam (whistle blower) lawsuit, in which Chiron and other companies are named defendants.

Certain State Attorneys General also are investigating reporting of average wholesale prices related to State Medicaid programs. In September 2000, the Office of the Attorney General of the State of California Department of Justice propounded a document subpoena to Chiron focused on pricing of certain generic oncology drugs sold by Cetus-Ben Venue under the Medi-Cal program. In December 2003, the Attorneys General for the States of Florida and Kentucky informed Chiron that they were investigating Chiron's calculation and reporting of the average manufacturer price and best price to the Center for Medicare and Medicaid Services and the Health Care Financing Administration.

It is anticipated that additional lawsuits involving the average wholesale price issues for these and other products sold by Chiron through Medicaid and/or Medicare may arise. If any such action resulted in a final judgment against Chiron, Chiron could face substantial damages exposure. It is not currently possible to estimate the probability of loss or to estimate the amount of liability related to these matters."

**ANSWER:** Chiron admits that Plaintiffs accurately quote a select portion from page 20 of Chiron's 2003 10-K Annual Report, and respectfully refers the Court to its 2003 10-K Annual Report for fiscal year ending December 31, 2003, which Chiron filed on or about March 3, 2004, for a full and complete reading of its contents. It is available at <http://www.secinfo.com/dVut2.1684.htm>.

**Paragraphs 399-769 (Allegations concerning various other Defendants)**

**ANSWER:** The allegations in Paragraphs 399-769 are directed to other defendants and require no response from Chiron. To the extent a response is deemed required, Chiron is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 399-769 and therefore denies the same and demands strict proof thereof.

**ANSWER TO DAMAGES TO THE COUNTY MEDICAID PROGRAMS**

770. The County Medicaid Programs spent over \$20 billion for defendants' drugs from 1992 - 2005. A substantial portion of this huge sum is the result of the inflation of prescription drug prices pursuant to the false price reporting scheme alleged herein, and the failure to pay the full rebate amounts required by law.

**ANSWER:** To the extent paragraph 770 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation in paragraph 770 that the Counties' Medicaid programs "spent over \$20 billion for defendants' drugs from 1992 – 2005[]" and therefore denies the same and demands strict proof thereof. Chiron specifically denies that it was involved in any "false price reporting scheme." Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 770 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

771. Applying even the most conservative estimates of improper AWP/FUL spread and failures to report accurate Best Prices or pay proper rebates, these abuses result in millions of dollars in excessive payments by the County Medicaid Programs for Medicaid-covered drugs.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 771 as to Chiron and therefore denies the same and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 771 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

772. The Counties now seek, *inter alia*, to recover the overpayment. Defendants' misconduct has unjustly enriched the defendants at the expense of New York's health care system, and ultimately, taxpayers in the Counties and State and nationwide.

**ANSWER:** Chiron denies the allegations in paragraph 772 of the Complaint as to Chiron and demands strict proof thereof. Chiron specifically denies that it was involved in any “misconduct,” or that it has been “unjustly enriched,” and therefore denies the same and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 772 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO FRAUDULENT CONCEALMENT**

773. By controlling the process by which the AWP's and other reimbursement price information for subject drugs were inflated and reported falsely to publishers, each defendant concealed its fraudulent conduct from the Counties. Each defendant prevented the Counties from knowing what the actual pricing structures for the covered drugs were, and concealed the standard discounts, chargebacks, off-invoice transactions, free samples and other financial incentives routinely provided to lower the actual costs for its drugs.

**ANSWER:** Chiron denies the allegations in paragraph 773 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 773 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

774. Each defendant who reported WAC or Direct Price or other reimbursement price information to the publishers concealed that the reimbursement prices did not accurately reflect the true prices at which defendants' products were sold.

**ANSWER:** Chiron denies the allegations in paragraph 774 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 774 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

775. Each defendant concealed that it sold the vast majority of its drugs pursuant to negotiated contracts at discounts off of WAC.

**ANSWER:** Chiron denies the allegations in paragraph 775 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 775 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

776. Each defendant concealed its fraudulent conduct by instructing drug distribution chain intermediaries not to report the prices they paid for the covered drugs.

**ANSWER:** Chiron denies the allegations in paragraph 776 of the Complaint as to Chiron and demands strict proof thereof, except admits that Chiron may keep certain competitively sensitive pricing information confidential. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 776 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

777. Each defendant worked with and motivated provider and drug distribution chain intermediaries to halt investigations or changes in the AWP/ reimbursement price system.

**ANSWER:** Chiron denies the allegations in paragraph 777 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 777 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

778. Each defendant concealed that its calculation of Medicaid rebates, based on Best Price and AMP, did not account for all discounts, rebates or incentives as required by law.

**ANSWER:** To the extent paragraph 778 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 778 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 778 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

779. Each defendant concealed that it was selling substantial quantities of its drugs for less than 10% of AWP to commercial entities to avoid Best Price reporting obligations, an abuse of the Nominal Price exception.

**ANSWER:** To the extent paragraph 779 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 779 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 779 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

780. Each defendant further concealed the true Best Prices from the federal agencies to which it reports those data.

**ANSWER:** To the extent paragraph 780 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 780 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 780 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

781. Each defendant concealed that it was not paying proper rebates to the states.

**ANSWER:** Chiron denies the allegations in paragraph 781 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 781 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

782. Each defendant purposely concealed its pricing structures, promotional practices and sales figures for the covered drugs.

**ANSWER:** Chiron denies the allegations in paragraph 782 of the Complaint as to Chiron and demands strict proof thereof, except admits that Chiron may keep certain competitively sensitive pricing information confidential. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 782 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

783. Each defendant concealed that it purposely inflated its reimbursement price information in order to create a marketable spread.

**ANSWER:** Chiron denies the allegations in paragraph 783 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 783 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

784. Each defendant's efforts to conceal its pricing structures for the drugs at issue is evidence that it knew that its conduct was fraudulent.

**ANSWER:** Chiron denies the allegations in paragraph 784 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 784 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

785. Thus, each defendant concealed that (i) its AWP's and Direct Prices and other reported wholesale prices were highly inflated for the express purpose of causing the Counties to overpay for the subject drugs, (ii) it was manipulating the AWP's of the subject drugs, (iii) the AWP's bore no relationship to the prices paid for, or the pricing structure of, the subject drugs and (iv) it was not accurately reporting its Best Prices and not accurately calculating its Medicaid rebates.

**ANSWER:** Chiron denies the allegations in paragraph 785 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 785 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

786. Deutsche Bank's Barbara Ryan, a large-cap pharmaceutical analyst concurs:

“[W]e all look at list price, because it's the only thing that is known to us. But list price is increasingly absolutely irrelevant. It's [more important] what goes on behind the curtain. Now we don't know what goes on behind the curtain, we can only imagine, but we can judge the results. So we see that some companies, like Pfizer, have been more successful behind the curtain than others. The breadth of your product portfolio and the importance of that portfolio to any payor certainly plays a role. If you have a one-off drug that you're trying to position and it might be in a therapeutic category that's quite crowded, it is very difficult to have any traction.”

*The Pink Sheet* 2004/2005 Almanac.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 786 and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 786 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

787. Unaware of the true facts about the pricing of the covered drugs, and statutorily obligated to a 25% Medicaid contribution, the Counties have paid and continue to pay for them based upon and in reliance on the AWP.

**ANSWER:** To the extent paragraph 787 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 787 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 787 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

788. The Counties have been diligent in pursuing an investigation of the claims asserted in this Complaint. Only in the wake of recent Congressional hearings, DOJ, OIG and HHS reports, and settlements have the Counties become informed of or placed on notice regarding the extent of defendants' fraudulent conduct.

**ANSWER:** Chiron denies the allegation in paragraph 788 of the Complaint as to Chiron regarding “defendants’ fraudulent conduct[]” and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 788 and therefore denies the same and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 788 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

789. The Counties have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on its part. The Counties could not reasonably have discovered the fraudulent nature of the published AWP’s and of the Medicaid rebate amounts calculated by defendants. Because of their knowing, affirmative, and active concealment of the fraudulent nature of pricing information, defendants are estopped from relying on any statutes of limitations.

**ANSWER:** To the extent paragraph 789 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 789 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 789 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

790. Any applicable statutes of limitations have been tolled by defendants’ knowing and active concealment and denial of the facts alleged herein. At all times relevant the defendants have been and are under a continuing duty to disclose to the Counties that the AWP’s they reported or caused to be reported bear no relationship to the actual prices paid for their drugs, that defendants manipulated the AWP’s to create a spread, and that the Medicaid rebates that they pay are reduced by the use of false and inaccurate pricing information, and abuse of the Nominal Price exception.

**ANSWER:** To the extent paragraph 790 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations in paragraph 790 of the Complaint as to Chiron and demands strict proof thereof.

Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 790 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO CLAIMS FOR RELIEF**

**ANSWER TO COUNT I – VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

791. The Counties reallege and incorporate the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 790, above.

792. Each of the defendant pharmaceutical companies is a manufacturer of a drug covered by Medicaid.

**ANSWER:** Chiron states that no response is required to paragraph 792 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 792 of the Complaint as to Chiron and demands strict proof thereof, except admits that certain state Medicaid programs have at certain times paid for a portion of certain Chiron drugs prescribed to their beneficiaries. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 792 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

793. Pursuant to 42 U.S.C. § 1396r-8, each of the defendant pharmaceutical manufacturers of single source and brand name innovator drugs entered into a rebate agreement with the Medicaid program pursuant to which the defendant agreed to report its Best Price.

**ANSWER:** To the extent paragraph 793 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 793 of the Complaint because this Court has already dismissed this cause of action. To the extent a

response is deemed required, Chiron denies the allegations set forth in paragraph 793 of the Complaint as to Chiron and demands strict proof thereof, except admits that Chiron is subject to a rebate agreement with the Secretary of the Department of Health and Human Services (“HHS”) pursuant to which Chiron reports certain pricing information to the federal government and remits rebate payments to the State of New York (and other participating states), and that these rebates lower the State of New York’s cost of prescription drugs for Medicaid patients. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 793 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

794. In keeping with their artificial price inflation scheme, each defendant did not report the actual Best Price but instead reported incorrect Best Prices by, *inter alia*, excluding routine discounts (*e.g.*, volume and prompt pay discounts and discounts to repackagers), rebates, off-invoice transactions, free samples and other inducements offered to participants in the drug distribution chain that resulted in lower prices than the prices reported to the Medicaid Program.

**ANSWER:** Chiron states that no response is required to paragraph 794 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 794 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 794 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

795. Each of the defendants violated 42 U.S.C. § 1396r-8 by their systematic submission of untrue, incomplete, inaccurate, and misleading information used to determine the amount of rebates under the Medicaid program.

**ANSWER:** To the extent paragraph 795 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 795 of the

Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 795 of the Complaint as to Chiron and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 795 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

796. As set forth herein, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each defendant made or caused to be made false statements and incorrect payments while promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

**ANSWER:** To the extent paragraph 796 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 796 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 796 of the Complaint as to Chiron and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 796 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

797. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of pricing information submitted and that the rebates they were paying were incorrectly calculated.

**ANSWER:** To the extent paragraph 797 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 797 of the Complaint because this Court has already dismissed this cause of action. To the extent a

response is deemed required, Chiron denies the allegations set forth in paragraph 797 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 797 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

798. As a result of defendants' inaccurate reporting of Best Price, defendants did not comply with their obligations pursuant to the Federal Medicaid rebate provision and the Counties were deprived of a portion of the rebates to which it was entitled.

**ANSWER:** To the extent paragraph 798 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 798 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 798 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 798 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

799. The Counties are within the class of entities for whose benefit the rebate provision was enacted.

**ANSWER:** To the extent paragraph 799 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 799 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 799 and therefore denies the same and demands strict proof thereof.

800. Medicaid pharmacy costs for Counties residents are higher than they would have been if defendants had accurately reported Best Price. The Counties have therefore suffered actual injury as a direct result of defendants' misconduct. That injury would be redressed through a favorable decision on this claim.

**ANSWER:** To the extent paragraph 800 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 800 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 800 and therefore denies the same and demands strict proof thereof.

**ANSWER TO COUNT II – VIOLATION OF N.Y. SOCIAL SERVICES LAW 367-a(7)(d)  
(FAILURE TO COMPLY WITH STATE MEDICAID REBATE PROVISION)**

801. The Counties reallege and incorporate the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 800, above.

802. Each of the defendant pharmaceutical companies is a manufacturer of a drug covered by Medicaid.

**ANSWER:** Chiron states that no response is required to paragraph 802 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 802 of the Complaint as to Chiron and demands strict proof thereof, except admits that certain state Medicaid programs have at certain times paid for a portion of certain Chiron drugs prescribed to their beneficiaries. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 802 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

803. The rebate provision, 42 U.S.C. § 1396r-8, is incorporated by New York State's Medicaid statute. *See* New York Social Services Law § 367-a(7)(d). New York law expressly provides that each of the defendants who have executed a rebate agreement are to be paid pursuant to that agreement.

**ANSWER:** To the extent paragraph 803 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 803 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 803 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 and New York Social Services Law § 367-a(7)(d) for a full and complete reading of their provisions.

804. As set forth herein, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each defendant made or caused to be made false statements and incorrect payments while promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

**ANSWER:** To the extent paragraph 804 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 804 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 804 of the Complaint as to Chiron and demands strict proof thereof, and respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 804 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

805. Each defendant thereby violated N.Y.Soc. Serv. L. § 367-a(7)(d) in that it submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of reimbursement under the Medicaid program and in that it paid incorrectly calculated rebates to the states.

**ANSWER:** To the extent paragraph 805 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 805 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 805 of the Complaint as to Chiron and demands strict proof thereof, and respectfully refers the Court to N.Y. Soc. Serv. L. § 367-a(7)(d) for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 805 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

806. Defendants knew, or by virtue of their position, authority and responsibility should have known, of the falsity of the pricing information submitted and that the rebates they were paying were incorrectly calculated.

**ANSWER:** To the extent paragraph 806 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 806 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 806 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 806 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

807. As a result of defendants' inaccurate reporting of Best Price, defendants did not comply with their obligations pursuant to the State Medicaid rebate provision and the Counties were deprived of a portion of the rebates to which it was entitled.

**ANSWER:** To the extent paragraph 807 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 807 of the Complaint because this Court has already dismissed this cause of action. To the extent a

response is deemed required, Chiron denies the allegations set forth in paragraph 807 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 807 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO COUNT III – VIOLATION OF NEW YORK SOCIAL SERVICES LAW  
145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)**

808. The Counties reallege and incorporate the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 807, above.

809. New York Social Services Law § 145-b provides that “[i]t shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for ... supplies furnished ... pursuant to” the Medicaid Program.

**ANSWER:** Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 809 of the Complaint and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 809 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

810. By engaging in the acts and practices described above, defendants have knowingly made false statements and representations or engaged in a fraudulent scheme on behalf of themselves and others, resulting in the overpayment of public funds for defendants’ prescription drugs covered by the New York Medicaid Program in violation of Soc. Serv. L. § 145-b.

**ANSWER:** To the extent paragraph 810 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 810 of the Complaint as to Chiron and demands strict proof

thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 810 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 810 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

811. Defendants' conduct violated and continues to violate Social Services Law § 145-b because defendants, and each of them, by means of their false statements and representations and deliberate concealment of material facts attempted to obtain and did in fact obtain payment from public funds for supplies furnished pursuant to this chapter. Defendants made false "statements or representations" under § 145-b(1)(b) because they gave "a [false] report of data which serves as the basis for a claim or a rate of payment."

**ANSWER:** To the extent paragraph 811 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 811 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 811 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 811 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

812. Defendants have "attempted to obtain and did obtain payment from public funds for supplies" under § 145-b(1)(c) because they obtained a portion of public funds from which payment was made, and because "public funds [we]re used to reimburse ... an entity from which payment was obtained." N.Y. Soc. Serv. L. § 145-b.

**ANSWER:** To the extent paragraph 812 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the

allegations set forth in paragraph 812 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 812 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 812 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

813. Defendants also have made false statements or representations “on behalf of others...to obtain payment from public funds in violation of N.Y. Soc. Serv. L. § 145-b. [sic]

**ANSWER:** To the extent paragraph 813 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 813 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 813 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. To the extent the allegations in paragraph 813 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Chiron respectfully refers the Court to New York Social Services Law § 145-b for a full and complete reading of its provisions.

**ANSWER TO COUNT IV – VIOLATION OF NEW DEPARTMENT OF HEALTH  
REGULATIONS 18 N.Y.C.R.R. 512.2(b)4) and (5)**

814. The Counties reallege and incorporate the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 813, above.

815. The Regulations of the New York City Department of Health, 18 N.Y.C.R.R. § 515.2(b)(4), provide that “[c]onversion of a medical assurance payment, or any part of such

payment, to a use or benefit other than for the use and benefit intended by the medical assistance program,” is an “unacceptable practice” within the New York Medicaid Program.

**ANSWER:** To the extent paragraph 815 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 815 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 815 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to Regulations of the New York City Department of Health, 18 N.Y.C.R.R. § 515.2(b)(4) for a full and complete reading of its provisions.

816. The Regulations of the New York Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5) provide that an “Unacceptable Practice” within the Medicaid program is committed by “offering or paying either directly or indirectly any payment (including any kickback, bribe, ... rebate or discount), whether in cash or in kind, in return for purchasing, ... ordering or recommending any medical care, services or supplies for which payment is claimed under the program,” “[u]nless the discount or reduction in price is disclosed to the client and the department and reflected in a claim,” [sic]

**ANSWER:** To the extent paragraph 816 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 816 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 816 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to Regulations of the New York City Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5) for a full and complete reading of its provisions.

817. By engaging in the acts and practices described above, defendants have engaged in and continue to engage in Unacceptable Practices within the New York Medicaid Program as defined at 18 N.Y.C.R.R. § 515.2(b)(4) and (5).

**ANSWER:** To the extent paragraph 817 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 817 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 817 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 817 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 18 N.Y.C.R.R. § 515.2(b)(4) and (5) for a full and complete reading of their provisions.

**ANSWER TO COUNT V – BREACH OF CONTRACT**

818. The Counties reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 817, above.

819. As required by 42 U.S.C. § 1396r-8, and to effectuate its purpose of reducing state Medicaid drug expenditures, each defendant entered into a Rebate Agreement with the Secretary of HHS.

**ANSWER:** To the extent paragraph 819 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 819 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 819 of the Complaint as to Chiron and demands strict proof thereof, except admits that Chiron is subject to a rebate agreement with the Secretary of HHS pursuant to which Chiron reports certain pricing information to the federal government and remits rebate payments to the State of New York (and other participating states), and that these rebates lower the State of New York's cost of prescription

drugs for Medicaid patients. Chiron respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 819 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

820. The Secretary of HHS entered into this Rebate Agreement, “on behalf of the States.”

**ANSWER:** To the extent paragraph 820 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 820 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron admits that Plaintiffs quote a select portion of the first paragraph before Section I of the Model Rebate Agreement, which is attached to Plaintiffs’ Complaint at Exhibit E, but denies that the quote is accurate and states that the Model Rebate Agreement speaks for itself, and any characterizations thereof are denied. Chiron further states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 820 and therefore denies the same and demands strict proof thereof.

821. The Medicaid statute provides that “the State *or local agency* administering such plan will take all reasonable measures to ascertain the legal liability of third parties for any overcharges and submit to the Secretary of Health and Human Services a plan for pursuing such claims. 42 U.S.C. § 1396a (a)(25)(A) (emphasis added).

**ANSWER:** To the extent paragraph 821 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 821 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 821 and therefore denies the same

and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. § 1396a (a)(25)(A) for a full and complete reading of its provisions.

822. In any case where such a legal liability is found to exist . . . and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek reimbursement for such reimbursement to the extent of such legal liability. 42 U.S.C. 1396a (a)(25)(B).

**ANSWER:** To the extent paragraph 822 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 822 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 822 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to 42 U.S.C. 1396a (a)(25)(B) for a full and complete reading of its provisions.

823. New York's plan requires local social service districts to pay 25 percent of their Medicaid pharmacy costs, N.Y. Soc. Serv. L. §§ 360a, 363. It expressly authorizes local social service districts to file suit and seek treble damages for any knowing overcharge the Medicaid program, N.Y. Soc. Serv. L. § 145-b, and provides that amounts collected under that provision shall be apportioned between the local social service district and the state. N.Y. Soc. Serv. L. § 145-(b)(2) ("Amounts collected . . . shall be apportioned between the local services district and the state.").

**ANSWER:** To the extent paragraph 823 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 823 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 823 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. §§ 360a, 363 and N.Y. Soc. Serv. L. § 145-(b) for a full and complete reading of their provisions.

824. At the time each defendant entered into a Rebate Agreement, the Secretary of HHS expressly had approved New York State's Medicaid plan, including these provisions that authorize local social service districts, like the Counties, to sue for Medicaid fraud and that expressly impose a 25% contribution on the Counties.

**ANSWER:** To the extent paragraph 824 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 824 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 824 of the Complaint as to Chiron and demands strict proof thereof. Chiron respectfully refers the Court to New York State's Medicaid Plan for a full and complete reading of its contents. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 824 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

825. New York Social Services Law § 367-a(7)(D) expressly states that if any defendant has entered into such rebate agreement with HHS, reimbursement for covered outpatient drugs shall be made only subject to 42 U.S.C. § 1396r-8.

**ANSWER:** To the extent paragraph 825 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 825 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 825 and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to New York Social Services Law § 367-a(7)(D) and 42 U.S.C. § 1396r-8 for a full and complete reading of their provisions.

826. The Counties, like New York State, were intended third-party beneficiaries of these rebate agreements.

**ANSWER:** To the extent paragraph 826 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 826 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 826 and therefore denies the same and demands strict proof thereof.

827. The Secretary of HHS acted as the Counties' and State's agent in executing the rebate agreements. The rebate agreements expressly provide that the Secretary is entering into the agreements "on behalf of the states." The Counties are local social services districts for the purposes of administration of the State Social Services Law, N.Y. Soc. Serv. L. §§ 55, 61-62, and is therefore subsumed under the State in New York's statutory scheme.

**ANSWER:** To the extent paragraph 827 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 827 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 827 of the Complaint as to Chiron and demands strict proof thereof. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. §§ 55, 61-62 for a full and complete reading of their provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 827 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

828. As set forth herein, contrary to the express requirements of the Rebate Agreements, each defendant did not report accurate Best Prices for its drugs or pay correct Medicaid rebates.

**ANSWER:** To the extent paragraph 828 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 828 of the Complaint because this Court has already dismissed this cause of action. To the extent a

response is deemed required, Chiron denies the allegations set forth in paragraph 828 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 828 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

829. Rather, each defendant reported false and inflated Best Prices that, among other things, excluded routine discounts including prompt pay and bundled discounts, rebates, chargebacks and other inducements and incentives offered to drug selecting entities to create market share, and abused the nominal price exception.

**ANSWER:** To the extent paragraph 829 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 829 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 829 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 829 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

830. Defendants have therefore breached their rebate agreements and caused massive foreseeable damage to the Counties, intended third-party beneficiaries of the rebate agreement.

**ANSWER:** To the extent paragraph 830 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 830 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 830 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 830 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO COUNT VI – UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law 349 *et seq.*)**

831. The Counties reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 830, above.

832. As set forth with particularity herein and in the Exhibits hereto, defendants have intentionally and wrongfully reported inaccurate, false and misleading wholesale pricing information for the covered drugs.

**ANSWER:** Chiron denies the allegations set forth in paragraph 832 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 832 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

833. As alleged herein, this pricing scheme was designed to increase demand for defendants' products and is consumer oriented.

**ANSWER:** Chiron denies the allegations set forth in paragraph 833 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 833 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

834. Defendants' intentional wrongful acts caused direct damage to tax paying consumers and the Counties by wrongfully increasing Medicaid expenditures on behalf of the Counties' Medicaid Programs.

**ANSWER:** Chiron denies the allegations set forth in paragraph 834 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 834 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

835. The defendants' intentional misconduct directly has damaged the public and the Counties. The Counties are statutorily required to pay 25% of the Medicaid pharmacy costs attributable to its Medicaid recipients. N.Y. Soc. Serv. L §§ 367-b, 363-b(2).

**ANSWER:** To the extent paragraph 835 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 835 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 835 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to N.Y. Soc. Serv. L §§ 367-b, 363-b(2) for a full and complete reading of their provisions.

836. New York's Medicaid statute expressly states, *inter alia*, that "[m]edical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare." N.Y. Soc. Serv. L. 363. Defendants' deceptive acts, as described herein, are in direct contravention of this statutorily articulated public policy. Defendants' practices were consumer-oriented and continue to have a broad impact on consumers and the taxpaying public.

**ANSWER:** To the extent paragraph 836 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 836 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 836 as they pertain to other defendants and therefore denies the same and demands strict proof thereof. Chiron respectfully refers the Court to N.Y. Soc. Serv. L. 363 for a full and complete reading of its provisions.

837. The Counties are required by State law to balance its budget. Every dollar spent on Medicaid is a dollar that cannot be spent elsewhere.

**ANSWER:** To the extent paragraph 837 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 837 and therefore denies the same and demands strict proof thereof.

838. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in that:

(a) Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the wholesale pricing information they submit does not reflect the true wholesale prices of the drug products they sell, and that the Best Prices they report are not the actual Best Prices offered to other commercial entities, but are instead inflated in order to drive up the prices paid for medications by the Counties and deny the Counties proper Medicaid rebates;

(b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true wholesale pricing information and true Best Prices paid for their medications, which they know are the bases of the Counties' Medicaid pharmacy cost payments, in order to drive up the prices paid by the Counties through Medicaid and deny the Counties proper Medicaid rebates;

(c) Defendants have knowingly made false representations in a transaction by representing that the wholesale pricing information provided is an accurate reflection of the wholesale prices paid for their drugs, and that their reported Best Prices are in fact the Best Prices offered to a commercial entity for their drugs; and

(d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the Best Price requirement of the Medicaid statute, New York's Social Services Law, § 367-a, and § 145-b. These statutory and regulatory violations serve, at minimum, as predicates for the violation of New York's Gen. Bus. Law § 349.

**ANSWER:** To the extent paragraph 838 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 838 of the Complaint as to Chiron and demands strict proof thereof. Chiron respectfully refers the Court to New York's Social Services Law, § 367-a, and § 145-b and New York's Gen. Bus. Law § 349 for a full and complete reading of their provisions. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 838 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

839. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of defendants' business and has caused great harm to the Counties and the consumers who live there. The Counties have suffered actual damages because it has had to

overpay millions of dollars in Medicaid pharmacy costs as a direct and proximate result of defendants' misleading and deceptive practices.

**ANSWER:** To the extent paragraph 839 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 839 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 839 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

#### **ANSWER TO COUNT VII – FRAUD**

840. The Counties reallege and incorporate the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 839, above.

841. As detailed in the Complaint and Exhibits hereto, defendants have engaged in actual fraudulent reporting of pricing information on which Medicaid reimbursements are based, and have acted intentionally and with actual malice.

**ANSWER:** To the extent paragraph 841 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 841 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 841 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

842. Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of overcharging the Counties and the Counties have relied upon such misrepresentations. Direct, proximate and foreseeable injury has occurred as a result of such foreseeable and statutorily required reliance.

**ANSWER:** To the extent paragraph 842 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 842 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 842 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

843. Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to the Counties, and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.

**ANSWER:** To the extent paragraph 843 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 843 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 843 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

844. New York's Social Service Law § 366-b expressly provides that "any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization of furnishing services or merchandise under this title, shall be guilty of a class A misdemeanor...".

**ANSWER:** To the extent paragraph 844 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 844 and therefore denies the same and demands strict proof thereof. Chiron

respectfully refers the Court to New York's Social Service Law § 366-b for a full and complete reading of its provisions.

845. Defendants' knowing and intentional submission of inflated AWP's or other wholesale pricing data to publishers for the express purpose of effectuating the AWP scheme alleged herein, and their knowing and intentional failures to report accurate Best Prices and failure to pay correct Medicaid rebates constitute intentional frauds pursuant to common law and New York Social Services Law § 366-b.

**ANSWER:** To the extent paragraph 845 states conclusions or characterizations of law, no response is required. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 845 of the Complaint as to Chiron and demands strict proof thereof, and respectfully refers the Court to New York Social Services Law § 366-b for a full and complete reading of its provisions. Chiron is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 845 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

#### **ANSWER TO COUNT VIII – UNJUST ENRICHMENT**

846. The Counties reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

**ANSWER:** Chiron repeats and incorporates by reference its responses to paragraphs 1 through 845, above.

847. To the extent the court determines there is no contractual relationship between the Counties and the defendants, as a direct and proximate result of the unlawful conduct described above, defendants have been and will continue to be unjustly enriched.

**ANSWER:** To the extent paragraph 847 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 847 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 847 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 847 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

848. Defendants have benefited from their unlawful acts through the increased sale of covered drugs with the greatest spread. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by the Counties' Medicaid Programs and other Medicaid payors.

**ANSWER:** To the extent paragraph 848 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 848 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 848 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 848 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

849. The Counties are entitled to an accounting and the establishment of a constructive trust consisting of all overcharges paid by the Counties' Medicaid Programs for covered drugs.

**ANSWER:** To the extent paragraph 849 states conclusions or characterizations of law, no response is required. Chiron also states that no response is required to paragraph 849 of the Complaint because this Court has already dismissed this cause of action. To the extent a response is deemed required, Chiron denies the allegations set forth in paragraph 849 of the Complaint as to Chiron and demands strict proof thereof. Chiron is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 849 as they pertain to other defendants and therefore denies the same and demands strict proof thereof.

**ANSWER TO PRAYER FOR RELIEF**

WHEREFORE, plaintiff the Counties pray for judgment against each and every defendant, jointly and severally, as follows:

850. Adjudging and decreeing that defendants engaged in the intentional fraudulent conduct alleged herein in violation of N.Y. Soc. Serv. L. §§ 367-a(7)(d), 366-b, 145-b and 42 U.S.C. § 1396r-8 and 18 N.Y.C.R.R. 515.2(b)(4) and (5).

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 850 as to Chiron and states that the Court has already dismissed the causes of action under N.Y. Soc. Serv. L. §§ 367-a(7)(d); 42 U.S.C. § 1396r-8; and, 18 N.Y.C.R.R. 515.2(b)(4) and (5).

851. Awarding the Counties actual, statutory, treble and all other available money damages, with interest, for defendants' violation of N.Y. Gen. Bus. Law § 349 in an amount to be determined at trial;

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 851 as to Chiron.

852. Awarding the Counties actual, statutory, treble, punitive and all other available money damages, with interest, for defendants' violation of N.Y. Soc. Serv. L. § 145-b in an amount to be determined at trial;

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 852 as to Chiron.

853. Awarding the Counties actual and compensatory damages in an amount to be determined at trial, with interest, for defendants' breach of contract;

**ANSWER:** Chiron states that no response is required to paragraph 853 of the Complaint because this Court has already dismissed this cause of action. To the extent that a response may be required, Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 853 as to Chiron.

854. Awarding the Counties actual and punitive damages in an amount to be determined at trial, with interest, for defendants' intentional fraud in respect of matters of significant public interest;

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 854 as to Chiron.

855. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at the Counties' Medicaid Programs' expense, and disgorgement of such monies, with interest;

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 855 as to Chiron.

856. Imposing a constructive trust and ordering defendants to pay restitution to the Counties' Medicaid Programs in the amount the Counties' Medicaid Programs have been overcharged for covered drugs, with interest;

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 856 as to Chiron.

857. Awarding plaintiff the costs of the suit, including reasonable attorneys' and experts' fees pursuant to N.Y. Gen. Bus. Law § 349, N.Y. Soc. Serv. L. § 145-b, and any other applicable federal and state statutes or common law.

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 857 as to Chiron.

858. Such other further and different relief as the Court deems just and proper.

**ANSWER:** Chiron denies that there is any basis in law or fact for Plaintiffs to obtain the relief requested in paragraph 858 as to Chiron.

Each and every allegation of the Complaint not specifically or qualifiedly admitted as set forth herein is hereby denied.

### **AFFIRMATIVE DEFENSES**

By alleging the matters set forth below, Chiron does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters, or that Plaintiffs are relieved of their burdens to prove each and every element of their claims and the damages, if any, to which they are entitled. As and for its affirmative defenses, Chiron alleges as follows:

#### **FIRST AFFIRMATIVE DEFENSE**

Plaintiffs fail to state a claim against Chiron upon which relief may be granted, and the Complaint should be dismissed.

#### **SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### **THIRD AFFIRMATIVE DEFENSE**

Plaintiffs have no standing or capacity to bring some or all of the claims raised in the Complaint.

#### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Chiron as alleged in the Complaint.

#### **FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are barred, in whole or in part, because Plaintiffs have not suffered damages as a result of the matters alleged in the Complaint.

#### **SIXTH AFFIRMATIVE DEFENSE**

To the extent Plaintiffs or the State of New York obtain recovery in any other proceeding predicated on the same factual allegations, Plaintiffs are barred from seeking recovery against

Chiron based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the state action doctrine.

**NINTH AFFIRMATIVE DEFENSE**

Any and all actions taken by Chiron with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, Federal Medicare Act and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder, and by the existence and terms of written rebate agreement(s) with the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and certain States, including the State of New York, entitled "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturers Identified in Section XI of this Agreement" (the "Rebate Agreement"), which was entered pursuant to 42 U.S.C. § 1396r-8 and pursuant to which Chiron reports certain specific pricing information to the federal government and remits rebate payments to the State of New York based on that information.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are preempted by the Commerce Clause or the dormant Commerce Clause of the United States Constitution.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are barred because Chiron has complied with all applicable regulations of the federal and state governments.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because they violate Chiron's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as under the Constitution of the State of New York, insofar as Plaintiffs seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Chiron's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs attempt to seek equitable relief against Chiron, they are not entitled to such relief because they have an adequate remedy at law.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") in 2003, which

requires participating prescription drug manufacturers to report Average Sales Price (“ASP”) quarterly and defines ASP as the manufacturer’s “sales to all purchasers . . . in the United States for such drug or biological in the calendar quarter; divided by the total number of such units of such drug or biological sold by the manufacturer in such quarter.” 42 U.S.C. §§ 1396r-8(b)(3)42 & 1395w-3a(c)(1).

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs’ claims against Chiron are barred, in whole or in part, due to their failure to join indispensable parties.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, because any injuries sustained by Plaintiffs were the result of their own conduct or the intervening or superceding conduct of third parties.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs’ claims against Chiron for damages are barred, in whole or in part: (i) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of Plaintiffs and the allocation of any fault, if any exists, attributable to Chiron; (ii) by the doctrine of consent and/or ratification to the extent that Plaintiffs have paid for products manufactured, marketed and sold by Chiron after the filing of Plaintiffs’ original Complaint; and (iii) because they are speculative and remote, and because of the impossibility of ascertaining and allocating those alleged damages.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Chiron is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs, with respect to the same alleged injuries.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Any damages recovered by the Plaintiffs from Chiron must be limited by the applicable statutory ceilings on recoverable damages.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs fail to allege facts or a cause of action against Chiron sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are misjoined with Plaintiffs' claims against other defendants and must be severed.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs and/or their agents knew and were aware at all relevant times that AWP was not an average wholesale price or the actual acquisition cost of drugs and made their reimbursement choices with such knowledge. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the U.S. Constitution and the Constitution of the State of New York, prohibiting the absolute and arbitrary abuse of power, preclude Plaintiffs from bringing claims and seeking damages as alleged in the Complaint.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs fail to state with particularity facts to support the claims of fraudulent conduct against Chiron in the Complaint.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs fail to allege facts or a cause of action against Chiron sufficient to support a claim for prejudgment interest or any other relief.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are barred, in whole or in part, because Chiron did not make any false statements to Plaintiffs or their agents. As to any statement asserted against Chiron that Plaintiffs allege to be false or misleading, Chiron had no reasonable grounds to believe, and did not believe at the time such statement was made, that the statement was false or misleading.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Chiron denies that Plaintiffs have valid claims against Chiron under General Business Law § 349 and New York Social Services Law § 145-b and for common law fraud. However, if such claims are found to exist, Chiron pleads all applicable defenses under General Business Law § 349 and New York Social Services Law § 145-b and to common law fraud.

**THIRTIETH AFFIRMATIVE DEFENSE**

Any allegedly fraudulent statement or conduct of Chiron was not consumer-oriented as required under General Business Law § 349.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Chiron's conduct was neither "deceptive," "misleading," or "unlawful" as required under General Business Law § 349.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs did not rely on the allegedly fraudulent statements or conduct of Chiron.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron under General Business Law § 349 are barred in whole or in part to the extent that the Act: (i) does not allow (or did not allow at the time the conduct was alleged herein) for recovery by indirect purchasers; and (ii) does not govern conduct that was primarily interstate in nature.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Chiron denies that Plaintiffs have valid consumer protection claims against Chiron under New York's Unfair Trade Practices Act. However, if such claims are found to exist, Chiron pleads all available defenses under the Act.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Any discounts that were provided by Chiron were earned discounts and therefore appropriate business decisions.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Any alleged misconduct by Chiron was not a substantial factor in Plaintiffs' decision to reimburse for Chiron's products.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

All rebates paid by Chiron to the State of New York should be taken into account in determining the amount of damages, if any, to which Plaintiffs are entitled.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Chiron are barred in whole or in part by the existence and terms of the written rebate agreement(s) between Chiron and the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and certain States, including the State of New York, entitled, "Rebate Agreement Between the Secretary of Health and Human Services and the

Manufacturer Identified in Section XI of this Agreement,” which was entered into pursuant to 42 U.S.C. §1396r-8 and requires Chiron to report to the federal government the average discounted unit prices for its drugs and to remit rebate payments to the State of New York based on those average discounted unit prices.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiffs’ claims for injunctive relief against Chiron are barred by the doctrines of *in pari delicto* and/or unclean hands.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs’ prayers for relief in the form of restitution are barred, in whole or in part, because Chiron did not retain any money belonging to the Plaintiffs as a result of any alleged overpayments, and by the existence of express, written agreements covering the subject matter of Plaintiffs’ claims.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, by the economic loss doctrine.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, by the voluntary payment doctrine.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Chiron in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**FORTY-FORTH AFFIRMATIVE DEFENSE**

To the extent punitive damages are sought, Plaintiffs’ punitive damages claims against Chiron: (i) have no basis in law or fact; (ii) are not recoverable because the allegations of the

Complaint are legally insufficient to support a claim for punitive damages against Chiron; (iii) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Chiron prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Chiron's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of New York; (iv) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Chiron's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of New York; (v) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Chiron for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Chiron's products would constitute impermissible multiple punishments for the same wrong, in violation of Chiron's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of New York; (vi) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Chiron's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York; and (vii) cannot be sustained

because any award of punitive damages, which are penal in nature, without according Chiron the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Chiron's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York.

#### **FORTY-FIFTH AFFIRMATIVE DEFENSE**

To the extent punitive damages are sought, Plaintiffs' claims for punitive damages against Chiron cannot be sustained because an award of punitive damages by a jury that: (i) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (ii) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (iii) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Chiron; (iv) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (v) is not properly instructed regarding Plaintiffs' burden of proof with respect to each and every element of a claim for punitive damages; and (vi) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Chiron's Due Process and Equal Protection

rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of New York.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

The “Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturers Identified in Section XI of this Agreement” (the “Rebate Agreement”), which was entered pursuant to 42. U.S.C. § 1396r-8, constitutes the entire agreement with the State of New York and governs the relationship between them, such that the provisions of General Business Law § 349 do not apply to the relations between the parties.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Chiron hereby adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Chiron states that its Affirmative Defenses are based upon, and necessarily limited by, information now available to Chiron as Case Management Order No. 33 had previously stayed discovery while Chiron’s individual Motion to Dismiss the New York Complaint was pending before the Court. To that end, Chiron gives notice that it intends to rely upon any other additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its Answer and Affirmative Defenses to assert such defense should it deem doing so necessary during the discovery process.

**PRAYER**

WHEREFORE, Chiron Corporation prays as follows:

- A. That all claims contained in Plaintiffs' Complaint against it be dismissed with prejudice;
- B. That it be awarded costs and attorneys' fees; and,
- C. That it have such other and further relief as this Court deems just and proper.

Respectfully submitted,

\_\_\_\_\_  
/s/

D. Jacques Smith, Esq.

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*Attorney for Defendant Chiron Corporation*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 29, 2008, I caused a true and correct copy of the foregoing to be served on all counsel of record via electronic service by sending a copy to LexisNexis File & Serve for posting and notification to all parties in this action pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ D. Jacques Smith